15 May 2020
EMA/269170/2020 draft 3
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Draft agenda of May 2020 meeting

Chair: D. Murphy

Vice-chair: G. J. Schefferlie

18 May 2020, 09:00 – 20 May 2002, 13:00 - Virtual meeting

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 previous meeting

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

Scientific Advice Working Party (virtual)	Friday, 15 May 2020	10:00-13:00

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1. ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS

1.1 Opinions

- No items

1.2 Oral explanations and list of outstanding issues

• **Substance** EMEA/V/MRL/003649/EXTN/0003 *Cattle*	***For decision:*** Need for oral explanation ***For adoption:*** List of outstanding issues
• **Substance** EMEA/V/MRL/005009/FULL/0002 *Cattle*	***For decision:*** Need for oral explanation

1.3 List of questions

• No items	

1.4 Re-examination of CVMP opinions

• No items	

1.5 Other issues

2. COMMUNITY MARKETING AUTHORISATIONS AND EXTENSIONS

2.1 Opinions

• **Product** EMEA/V/C/005057/0000 *New vaccine* *Chickens*	***For adoption:*** CVMP opinion, CVMP assessment report, product information ***For information:*** Summary of opinion
• **Product** EMEA/V/C/005058/0000 *New vaccine* *Chickens*	***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/005305/0000 *New product* *Cattle, pigs, sheep*	***For decision:*** Need for an oral explanation ***For adoption:*** Scientific overview and list of outstanding issues, comments on product information
• **Product** EMEA/V/C/005076/0000 *New product* *Cattle, pigs, sheep*	***For decision:*** Need for an oral explanation ***For adoption:*** Scientific overview and list of outstanding issues, comments on product information

• **Product** EMEA/V/C/005272/0000 *New vaccine* *Pigs*	***For decision:*** Need for an oral explanation ***For adoption:*** Scientific overview and list of outstanding issues, comments on product information
• **Product** EMEA/V/C/005190/0000 *New vaccine* *Chickens*	***For decision:*** Need for an oral explanation ***For adoption:*** Scientific overview and list of outstanding issues, comments on product information
• **Product** EMEA/V/C/005219/0000 *New product* *Pigs*	***For decision:*** Need for an oral explanation ***For adoption:*** Scientific overview and list of outstanding issues, comments on product information

2.3 List of questions

• No items	

2.4 Re-examination of CVMP opinions

• No items	

2.5 Other issues

• **Product** EMEA/V/C/005149/0000 *New vaccine* *Pigs*	***For decision:*** Request to extend the clock-stop
• **Product** EMEA/V/C/005148/0000 *New vaccine* *Pigs*	***For decision:*** Request to extend the clock-stop
• **Product** EMEA/V/C/005094/0000 *New product* *Cats*	***For decision:*** Request to extend the clock-stop

- ***For information:*** EPAR scientific discussion for **Tulissin** (EMEA/V/C/005073/0000), **Tulaven** (EMEA/V/C/005153/0000) and **Lydaxx** (EMEA/V/C/005199/0000)

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

• **Aivlosin** EMEA/V/C/000083/II/0078 *To add a new indication*	Rapp: C. Bergman Co-Rapp: A. Golombiewski ***For adoption:*** CVMP opinion, CVMP assessment report, product information ***For information:*** Summary opinion
• **Zulvac BTV** EMEA/V/C/004185/II/0004 *To vary the existing multi-strain dossier*	Rapp: F. Klein Co-rapp: P. Pasquali ***For adoption:*** CVMP opinion, CVMP assessment report, product information ***For information:*** Summary opinion
• **Leucofeligen FeLV/RCP** EMEA/V/C/000143/II/0012 *To change the onset of immunity*	Rapp: E. Werner Co-rapp: E. Augustynowicz ***For adoption:*** CVMP opinion, CVMP assessment report, product information ***For information:*** Summary opinion
• **Metacam** and **Novem** EMEA/V/C/xxxxxx/WS1813 *To update the SPC*	Rapp: C. Bergman ***For adoption:*** CVMP opinion ***For endorsement:*** Rapporteur's assessment report
• **Reconcile** EMEA/V/C/000133/II/0033 *Quality-related changes*	Rapp: S. Louet ***For adoption:*** CVMP opinion ***For endorsement:*** Rapporteur's assessment report
• **ERYSENG PARVO**, **ERYSENG** and **RHINISENG** EMEA/V/C/xxxx/WS1686 *Quality-related changes*	Rapp: J. G. Beechinor ***For adoption:*** CVMP opinion ***For endorsement:*** Rapporteur's assessment report
• **Purevax RC, Purevax RCP** and **Purevax RCPCH** EMEA/V/C/xxxxx/WS1732/G *Quality-related changes*	Rapp: B. Urbain ***For adoption:*** CVMP opinion, product information ***For endorsement:*** Rapporteur's assessment report
• **Purevax RCPCh FeLV, Purevax FeLV** and **Purevax RCP FeLV** EMEA/V/C/xxxxx/WS1733/G *Quality-related changes*	Rapp: B. Urbain ***For adoption:*** CVMP opinion, product information ***For endorsement:*** Rapporteur's assessment report

3.2 Oral explanations and list of outstanding issues

• **Posatex** EMEA/V/C/000122/II/0028/G *Quality-related changes*	Rapp: S. Louet ***For adoption:*** List of outstanding issues

3.3 List of questions

• **Simparica** and **MiPet Easecto** EMEA/V/C/xxxxx/WS1793 *Quality related changes*	Rapp: J. G. Beechinor ***For adoption:*** List of questions
• **Nasym** EMEA/V/C/004897/II/0003/G *Quality-related changes*	Rapp: J. G. Beechinor ***For adoption:*** List of questions, comments on product information

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

• **Dinolytic 12.5 mg/ml and 5 mg/ml solutions for injection and associated names, and generic products thereof** EMEA/V/A/136 *Withdrawal periods*	Rapp: S. Louet Co-rapp: G. J. Schefferlie ***For discussion*:** Rapporteur's assessment report and co-rapporteur's assessment report

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

• **Suvaxyn PRRS MLV** EU/2/17/215/001-003 *Animal health*	Rapp: E. Werner Co-rapp: F. Klein ***For adoption:*** CVMP opinion, CVMP assessment report

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

5.1 General issues

- No items

5.2 Post-authorisation measures and annual reassessments

- No items

5.3 Product anniversary list

Product	**Period**
Afoxolaner Merial (EMEA/V/C/005126)	20.05.2019 – 19.05.2020
Baycox Iron (EMEA/V/C/004794)	20.05.2019 – 19.05.2020
Bravecto Plus (EMEA/V/C/004440)	08.05.2019 – 07.05.2020
Credelio (EMEA/V/C/004247)	25.04.2019 – 24.04.2020
Cytopoint (EMEA/V/C/003939)	25.04.2019 – 24.04.2020
Equilis StrepE (EMEA/V/C/000078)	07.05.2019 – 06.05.2020
Felisecto Plus (EMEA/V/C/005093)	26.04.2019 – 25.04.2020
Improvac (EMEA/V/C/000136)	11.05.2019 – 10.05.2020
Naxcel (EMEA/V/C/000079)	19.05.2019 – 18.05.2020
Oncept IL-2 (EMEA/V/C/002562)	03.05.2019 – 02.05.2020
ReproCyc ParvoFLEX (EMEA/V/C/004858)	26.04.2019 – 25.04.2020
Respiporc FLUpan H1N1 (EMEA/V/C/003993)	17.05.2019 – 16.05.2020
Versican Plus DHPPi/L4 (EMEA/V/C/003678)	07.05.2019 – 06.05.2020
Versican Plus DHPPi/L4R (EMEA/V/C/002759	07.05.2019 – 06.05.2020
Zeleris (EMEA/V/C/004099)	15.05.2019 – 14.05.2020
Zulvac BTV (EMEA/V/C/004185)	25.04.2019 – 24.04.2020
Zuprevo (EMEA/V/C/002009)	06.05.2019 – 05.05.2020

5.4 Renewals

• **Fortekor Plus** EMEA/V/C/002804/R/0018	Rapp: N. C. Kyvsgaard Co-rapp: C. Muñoz Madero ***For adoption:*** CVMP opinion, CVMP assessment report, product information
• **Vectormune ND** EMEA/V/C/003829/R/0013	Rapp: F. Klein Co-rapp: E. Werner ***For adoption:*** CVMP opinion, CVMP assessment report, product information

5.5 Pharmacovigilance - PSURs and SARs

• **Clynav** EMEA/V/C/002390	Rapp: J. G. Beechinor ***For endorsement:*** Rapporteur's assessment report on the PSUR for the period 01.07.2019-31.12.2019
• **Draxxin** EMEA/V/C/000077	Rapp: A. Golombiewski ***For endorsement:*** Rapporteur's assessment report on the PSUR for the period 01.12.2018-30.11.2019
• **Halagon** EMEA/V/C/004201	Rapp: C. Muñoz Madero ***For endorsement:*** Rapporteur's evaluation on the PSUR for the period 01.07.2019-31.12.2019
• **Isemid** EMEA/V/C/004345	Rapp: C. Muñoz Madero ***For endorsement:*** Rapporteur's assessment report on the PSUR for the period 01.08.2019-31.01.2020
• **Porcilis ColiClos** EMEA/V/C/002011	Rapp: E. Werner ***For endorsement:*** Rapporteur's assessment report on the PSUR for the period 01.01.2017-31.12.2019
• **Poulvac E. coli** EMEA/V/C/002007	Rapp: E. Werner ***For endorsement:*** Rapporteur's assessment report on the PSUR for the period 01.01.2019-31.12.2019
• **Syvazyl BTV** EMEA/V/C/004611	Rapp: C. Muñoz Madero ***For endorsement:*** Rapporteur's assessment report on the PSUR for the period 01.08.2019-31.01.2020
• **Vectra Felis** EMEA/V/C/002746	Rapp: A. Golombiewski ***For endorsement:*** Rapporteur's assessment report on the PSUR for the period 01.01.2019-31.12.2019

- ***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***: Draft concept paper on the development of further guidance around medicated premixes – version including draft EU comments

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)

- ***For adoption:*** Revised combined VeDDRA list of clinical terms for reporting suspected adverse reactions in animals and humans to veterinary medicinal products; list of changes to combined VeDDRA list of clinical terms; guidance notes on the use of VeDDRA terminology for reporting suspected adverse reactions in animals and humans

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 discussion:*** Draft CVMP strategy on antimicrobials 2021-2025

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

- 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***: Draft minutes of the 23 April 2020 meeting; draft agenda of the meeting held on 19-20 May 2020

12. ORGANISATIONAL AND STRATEGIC MATTERS

- ***For information***: Guiding principles for a Regulatory Network COVID-19 Business Continuity Plan
- ***For information***: EC/HMA/EMA Notice to Stakeholders with questions and answers on regulatory expectations for veterinary medicinal products during the COVID-19 pandemic (link)

13. LEGISLATION

- ***For adoption:*** Scientific recommendations for implementing measures under Article 77(6) of Regulation (EU) 2019/6 on veterinary medicinal products regarding good pharmacovigilance practices
- ***For adoption:*** Scientific recommendations for implementing measures under Article 77(6) of Regulation (EU) 2019/6 on veterinary medicinal products regarding pharmacovigilance master file
- ***For information:*** Verbal update on work progress of the expert groups concerning provision of scientific recommendations on delegated and implementing acts to Regulation (EU) 2019/6; on rules for oral administration of veterinary medicinal products; and on the list of antimicrobials reserved for the treatment of certain infections in humans

14. ANY OTHER BUSINESS

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

ANNEX

	CVMP	ADVENT	AWP	ERAWP	EWP	IWP	PhVWP	QWP	SAWP	SWP	J3Rs WG
May 2020	18-20						12-13	4-6	15		
Jun 2020	16-18								16		
Jul 2020	14-16						7-8		14		
Sept 2020	8-10						22-23	16-18	10		
Oct 2020	6-8								6		