15 March 2019
EMA/CVMP/159614/2019 draft 3
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Draft agenda of March 2019 meeting

Chair: D. Murphy

Vice-chair: H. Jukes

19 March 2019, 09:00 – 21 March 2019, 13:00 - Room 1C

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 (room 1C)	Tue 19 March 2019	16.30-20.00

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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/003649/EXTN/0002 *Porcine*	***For information****:* Clock stop extension request

2. COMMUNITY MARKETING AUTHORISATIONS AND EXTENSIONS

2.1 Opinions

• **Product** EMA/V/C/005126/0000 *New product* *Dogs*	***For adoption:*** CVMP opinion, CVMP assessment report, product information ***For information:*** Summary of opinion
• **Product** EMEA/V/C/004794/0000 *New product* *Porcine*	***For adoption***: CVMP opinion, CVMP assessment report, product information ***For information:*** Summary of opinion
• **Innovax ND-IBD** EMEA/V/C/004422/X/0001 *Extension* *Chickens*	Rapp: J. Poot Co-rapp: E. Werner ***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/004973/0000 *New product* *Cats and dogs*	***For decision:*** Need for oral explanation ***For adoption:*** Scientific overview and list of outstanding issues, comments on product information

• **Product** EMEA/V/C/004897/0000 *New vaccine* *Cattle*	***For decision:*** Need for 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

Information on certain topics discussed under section 2.4 cannot be released at the present time as it is deemed to be confidential

2.5 Other issues

- ***For adoption:*** EPAR module scientific discussion for **Felisecto Plus** (EMEA/V/C/005093/0000)
- ***For adoption:*** EPAR module scientific discussion for **Chanhold** (EMEA/V/C/004824/0000)

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

• **ProZinc** EMEA/V/C/002634/II/0015 *To add a new target species*	Rapp: R. Breathnach Co-Rapp: S. Louet ***For adoption:*** CVMP opinion, CVMP assessment report, product information ***For information:*** Summary of opinion
• **Vectra 3D** EMEA/V/C/002555/II/0011 *Change in the legal status*	Rapp: G. Hahn Co-rapp: F. Hasslung Wikström **For adoption**: CVMP opinion, CVMP assessment report, product information ***For information:*** Summary of opinion
• **ProZinc** EMEA/V/C/002634/II/0016 *Quality*	Rapp: R. Breathnach ***For adoption:*** CVMP opinion ***For endorsement:*** Rapporteur's assessment report
• **CLYNAV** EMEA/V/C/002390/II/0004/G *Quality*	Rapp: J. G. Beechinor ***For adoption:*** CVMP opinion ***For endorsement:*** Rapporteur's assessment report
• **CYTOPOINT** EMEA/V/C/003939/II/0003/G *Quality*	Rapp: R. Breathnach ***For adoption***: CVMP opinion ***For endorsement:*** Rapporteur's assessment report

• **MS-H Vaccine** EMEA/V/C/00161/II/0013 *Quality*	Rapp: B. Urbain ***For adoption:*** CVMP opinion, product information ***For endorsement:*** Rapporteur's assessment report
• **Simparica** and **MiPet Easecto** EMEA/V/C/xxxxxx/WS1553 *To update the product information to implement the outcome of a PSUR assessment*	Rapp: G. J. Beechinor ***For adoption***: CVMP opinion, product information - Simparica, product information - MiPet Easecto ***For endorsement***: Rapporteur's assessment report

3.2 Oral explanations and list of outstanding issues

• **Coliprotec F4/F18** EMEA/V/C/ 004225/II/0005 *To add a new therapeutic indication*	Rapp: R. Cooney Co-Rapp: E. Augustynowicz ***For decision:*** Need for oral explanation ***For adoption:*** List of outstanding issues, CVMP assessment report, product information

3.3 List of questions

• **Bravecto** EMEA/V/C/002526/II/0033/G *To add new therapeutic indications*	Rapp: G. J. Schefferlie Co-rapp: R. Breathnach ***For adoption***: List of questions
• **Advocate** EMEA/V/C/000076/II/0041/G *To add new therapeutic indications and to amend the product information*	Rapp: T.-M. Muhonen Co-rapp: J. P. Duarte Da Silva ***For adoption***: 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

- No items

4.2 Article 34 of Directive 2001/82/EC

- No items

4.3 Article 35 of Directive 2001/82/EC

• **Veterinary medicinal products containing paromomycin to be administered parenterally to pigs** EMEA/V/A/129 *Indications, posology, withdrawal periods*	Rapp: B. Urbain Co-rapp: S. Louet ***For decision***: Need for outstanding issues ***For discussion***: Rapporteur's assessment report including co-rapporteur's critique

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

- No items

5.3 Product anniversary list

Product	Period
Bovalto Ibraxion (EMEA/V/C/000051)	09.03.2018 – 08.03.2019
CaniLeish (EMEA/V/C/002232)	14.03.2018 – 13.03.2019
Coliprotec F4 (EMEA/V/C/003797)	16.03.2018 – 15.03.2019
Econor (EMEA/V/C/000042)	12.03.2018 – 11.03.2019
Equisolon (EMEA/V/C/002382)	12.03.2018 – 11.03.2019
Fungitraxx (EMEA/V/C/002722)	12.03.2018 – 11.03.2019
Novem (EMEA/V/C/000086)	02.03.2018 – 01.03.2019
Pexion (EMEA/V/C/002543)	25.02.2018 – 24.02.2019
Porcilis Porcoli Diluvac Forte (EMEA/V/C/000024)	29.02.2018 – 28.02.2019

Product	Period
ProteqFlu (EMEA/V/C/000073)	06.03.2018 – 05.03.2019
ProteqFlu-Te (EMEA/V/C/000074)	06.03.2018 – 05.03.2019
Purevax RC (EMEA/V/C/000091)	23.02.2018 – 22.02.2019
Purevax RCP (EMEA/V/C/000090)	23.02.2018 – 22.02.2018
Purevax RCP FeLV (EMEA/V/C/000089)	23.02.2018 – 22.02.2018
Purevax RCPCh (EMEA/V/C/000088)	23.02.2018 – 22.02.2018
Purevax RCPCh FeLV (EMEA/V/C/000085)	23.02.2018 – 22.02.2018
ZULVAC 1+8 Bovis (EMEA/V/C/002473)	08.03.2018 – 07.03.2019
ZULVAC 1+8 Ovis (EMEA/V/C/002251)	14.03.2018 – 13.03.2019

5.4 Renewals

• **Versican Plus Pi/L4R** EMEA/V/C/003682/R/0013	Rapp: E. Werner Co-rapp: G. Kulcsár ***For adoption***: CVMP opinion, CVMP assessment report, product information
• **Suvaxyn PCV** EMEA/V/C/000149/R/0028	Rapp: B. Urbain Co-rapp: E.-M. Vestergaard ***For adoption:*** CVMP opinion, CVMP assessment report, product information
• **OSURNIA** EMEA/V/C/003753/R/0014	Rapp: S. Louet Co-rapp: F. Hasslung Wikström ***For adoption***: List of outstanding issues
• **Nobilis IB Primo QX** EMEA/V/C/002802/R/0006	Rapp: J.-C. Rouby Co-rapp: E. Werner ***For adoption***: CVMP opinion, CVMP assessment report, product information

5.5 Pharmacovigilance - PSURs and SARs

• **CaniLeish** EMEA/V/C/0002232	Rapp: J.-C. Rouby ***For endorsement***: Rapporteur's assessment report on the PSUR for the period 01.10.2015-30.09.2018
• **Cimalgex** EMEA/V/C/000162	Rapp: F. Hasslung Wikström ***For endorsement***: Rapporteur's assessment report on the PSUR for the period 01.09.2015-31.08.2018

• **EVALON** EMEA/V/C/004013	Rapp: R. Cooney ***For endorsement***: Rapporteur's assessment report on the PSUR for the period 01.05.2018-31.10.2018
• **Imestor** EMEA/V/C/002763	Rapp: E.-M. Vestergaard ***For endorsement***: Rapporteur's assessment report on the PSUR for the period 01.04.2018-30.09.2018
• **LETIFEND** EMEA/V/C/003865	Rapp: C. Muñoz ***For endorsement***: Rapporteur's evaluation on the PSUR for the period 01.05.2018-31.10.2018 & annex
• **Procox** EMEA/V/C/002006	Rapp: F. Hasslung Wikström ***For endorsement***: Rapporteur's assessment report on the PSUR for the period 01.11.2015-31.10.2018
• **Veraflox** EMEA/V/C/000159	Rapp: G. Hahn ***For endorsement***: Rapporteur's assessment report on the PSUR for the period 01.11.2015-31.10.2018

- ***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***: VICH GL57 on marker residue depletion studies to establish product withdrawal periods in aquatic species
- ***For adoption***: VICH GL36(R2) on general approach to establish a microbiological ADI
- ***For endorsement***: VICH GL16 on efficacy of antihelmintics – specific recommendations for porcines – claims for *Ascaris suum;* draft EU comments
- ***For endorsement***: Revision of VICH GL 23 on genotoxicity testing – EU comments on the revised draft decision tree provided by expert working group chair
- ***For endorsement***: Draft guideline on harmonisation of criteria to waive laboratory animal batch safety testing for vaccines for veterinary use – draft for circulation to the expert working group; overview of comments received on previous draft
- ***For information***: Verbal report on the teleconference of VICH EWG for a general guideline on pharmaceutical combination products, held on 13 March 2019
- ***For information***: Report from 37th Steering Committee meeting, 11th VICH Outreach Forum meeting and 6th VICH Conference, held between 24 February and 1 March in Cape Town, South Africa; Steering Committee agenda, Outreach Forum agenda, Conference programme

6.2 Codex Alimentarius

- ***For information***: Report of the 6th session of the Codex Ad Hoc intergovernmental task force on AMR, held on 10–14 December 2018 in Busan, Republic of Korea - *please see also 8.3*

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 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

- No items

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 information***: Communication from the European Commission outlining actions addressing the release of pharmaceuticals in the environment (link), Q&A – Strategic approach to pharmaceuticals in the environment (link).

8.3 Antimicrobial resistance

- ***For information***: Report of the 6th session of the Codex Ad Hoc intergovernmental task force on AMR, held on 10–14 December 2018 in Busan, Republic of Korea - *please see also 6.3*

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 meeting held on 21-22 February 2019; draft agenda of the meeting to be held on 21-22 March 2019

12. ORGANISATIONAL AND STRATEGIC MATTERS

- ***For discussion***: Draft agenda of the upcoming informal presidency CVMP/CMDv meeting (to be held during the Romanian presidency) on 6-8 May 2019 at Lake Balaton, Hungary
- ***For discussion***: Handling of confidential information within the EU network
- ***For information***: Upcoming election of the chair of the Committee for Medicinal Products for Veterinary Use (CVMP) at the May 2019 CVMP meeting; calls for nominations

13. LEGISLATION

- ***For information***: Outcome of the written procedure for endorsement of the mandates for the expert groups for provision of scientific advice on delegated and implementing acts to Regulation 2019/6 on veterinary medicinal products concerning: revision of Annex II - biologicals and novel therapies expert group; revision of Annex I - non-biologicals expert group; collection of data on antimicrobials; criteria to design antimicrobials reserved to humans; list of variations not requiring assessment; good pharmacovigilance practice - AEs/signal management, good pharmacovigilance practice - inspections, good pharmacovigilance practice - communication; pharmacovigilance system 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 2019/6 on veterinary medicinal products

14. ANY OTHER BUSINESS

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

ANNEX

	CVMP	ADVENT	AWP	ERAWP	EWP	IWP	PhVWP	QWP	SAWP	SWP	J3Rs WG
Mar 2019	19-21						26-27		19		
Apr 2019	15-17								15		
May 2019	21-23						28-29		21		
Jun 2019	18-20								18		
Jul 2019	16-18						9-10				