29 November 2019
EMA/653381/2019 draft 3
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Draft agenda of December 2019 meeting

Chair: D. Murphy

Vice-chair: G. J. Schefferlie

3 December 2019, 09:00 – 5 December 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 3 December 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

- No items

2. COMMUNITY MARKETING AUTHORISATIONS AND EXTENSIONS

2.1 Opinion

- No items

2.2 Oral explanations and list of outstanding issues

• **Product** EMEA/V/C/005153/0000 *New product* *Cattle, pigs, sheep*	***For decision:*** Need for oral explanation ***For adoption****:* Scientific overview and list of outstanding issues, comments on product information

2.3 List of questions

• **Product** EMEA/V/C/005190/0000 *New vaccine* *Chickens*	***For adoption***: CVMP scientific overview and list of questions, comments on product information

2.4 Re-examination of CVMP opinions

- No items •

2.5 Other issues

- ***For endorsement:*** EPAR scientific discussion for **Miratаz** (EMEA/V/C/004733/0000)
- ***For endorsement:*** EPAR scientific discussion for **Neptra** (EMEA/V/C/004735/0000)

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

• **Onsior** EMEA/V/C/000127/II/0024/G *To add a new therapeutic indication*	Rapp: G. J. Schefferlie Co-rapp: N. C. Kyvsgaard ***For adoption***: CVMP opinion, CVMP assessment report, product information ***For information:*** Summary of opinion
• **Nobilis IB 4-91** EMEA/V/C/000036/II/0026 *To amend the product information*	Rapp: J.-C. Rouby ***For adoption:*** CVMP opinion, CVMP assessment report, product information
• **Eravac** EMEA/C/V/004239/II/0005/G *To extend the duration of immunity*	Rapp: C. Muñoz ***For adoption****:* CVMP opinion, CVMP assessment report, product information ***For information:*** Summary of opinion
• **Zulvac SBV** EMEA/V/C/002781/II/0006 *Quality-related changes*	Rapp: G. Kulcsár ***For adoption****:* CVMP opinion, product information ***For endorsement:*** Rapporteur's assessment report
• **Bravecto and Bravecto Plus** EMEA/V/C/xxxxxx/WS1721 *Quality-related changes*	Rapp: G. J. Schefferlie ***For adoption:*** CVMP opinion ***For endorsement:*** Rapporteur's assessment report
• **Apoquel** EMEA/V/C/002688/II/0017/G *Quality-related changes*	Rapp: R. Breathnach ***For adoption*:** CVMP opinion, product information ***For endorsement*:** Rapporteur's assessment report
• **Circovac** EMEA/V/C/000114/II/0016/G *Quality-related changes*	Rapp: P. Pasquali ***For adoption*:** CVMP opinion, product information ***For endorsement*:** Rapporteur's assessment report
• **Innovax ILT** EMEA/V/C/003869/II/0004 *Quality-related changes*	Rapp: E. Werner ***For adoption***: CVMP opinion ***For endorsement:*** Rapporteur's assessment report
• **Simparica / MiPet Easecto** EMEA/V/C/xxxxxx/WS1709 *Quality-related changes*	Rapp: J. G. Beechinor ***For adoption***: CVMP opinion ***For endorsement:*** Rapporteur's assessment report

• **ZACTRAN** EMEA/V/C/000129/II/0042/G *Quality-related changes*	Rapp: N. C. Kyvsgaard ***For adoption***: CVMP opinion ***For endorsement*:** Rapporteur's assessment report

3.2 Oral explanations and list of outstanding issues

• **CLYNAV** EMEA/V/C/002390/II/0010 *To extend the duration of immunity*	Rapp: J. G. Beechinor ***For adoption:*** List of outstanding issues, comments on product information

3.3 List of questions

• **ERYSENG PARVO, ERYSENG** and **RHINISENG** EMEA/V/C/WS1686 *Quality-related changes*	Rapp: J. G. Beechinor ***For adoption*:** List of questions

3.4 Re-examination of CVMP opinions

• **Velactis** EMEA/V/C/003739/II/0004 *Update of product information and submission of new data to demonstrate the safe use of the product*	Rapp: R. Breathnach Co-rapp: C. Muñoz **ORAL EXPLANATION – Tuesday 3 December 2019, 11:00-12:00** ***For adoption:*** Final CVMP opinion, CVMP assessment report ***For discussion:*** Applicant's presentation ***For information:*** Summary of opinion

3.5 Other issues

Information on certain topics discussed under section 3.5 cannot be released at the present time as it is deemed to be confidential

4. REFERRALS AND RELATED PROCEDURES

4.1 Article 33 of Directive 2001/82/EC

• **Ketabel 100 mg/ml solution for injection and associated names** EMEA/V/A/133 *Withdrawal period*	Rapp: G. Hahn Co-rapp: S. Louet ***For adoption:*** CVMP opinion and CVMP assessment report

4.2 Article 34 of Directive 2001/82/EC

• **Adjusol and its associated names** EMEA/V/A/134 *Harmonisation of SPC*	Rapp: C. Muñoz Co-rapp: S. Louet ***For adoption:*** List of outstanding issues, revised timetable ***For discussion***: Rapporteur's assessment report including co-rapporteur's critique, draft product information

4.3 Article 35 of Directive 2001/82/EC

• **Veterinary medicinal products containing tylosin base (as single active substance) presented as solutions for injection for intramuscular use in pigs** EMEA/V/A/131 *Withdrawal periods*	Rapp: S. Louet Co-rapp: L. Nepejchalová ***For adoption:*** CVMP opinion and CVMP 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 (EC) No 726/2004

- No items

4.7 Article 45 of Regulation (EC) No 726/2004

• **Suvaxyn PRRS MLV** U/2/17/215/001-003	Rapp: E. Werner Co-rapp: F. Klein ***For adoption:*** List of questions, timetable

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

5.1 General issues

- No items

5.2 Post-authorisation measures and annual reassessments

• **Ingelvac CircoFLEX** EMEA/V/C/000126/REC/016 *Recommendation*	Rapp: P. Pasquali Co-rapp: B. Urbain ***For adoption:*** Rapporteur's assessment report

• **ProtecFlu** EMEA/V/C/000073/REC.039 *Recommendation*	Rapp: J.-C. Rouby ***For adoption:*** Rapporteur's assessment report
• **ProtecFlu-Te** EMEA/V/C/000074/REC.043 *Recommendation*	Rapp: J.-C. Rouby ***For adoption:*** Rapporteur's assessment report

5.3 Product anniversary list

Product	**Period**
Bovilis Blue-8 (EMEA/V/C/004776)	21.11.2018 – 20.11.2019
Broadline (EMEA/V/C/002700)	04.12.2018 – 03.12.2019
Draxxin (EMEA/V/C/000077)	11.11.2018 – 10.11.2019
Easotic (EMEA/V/C/000140)	20.11.2018 – 19.11.2019
Equip WNV (EMEA/V/C/000137)	21.11.2018 – 20.11.2019
Masivet (EMEA/V/C/000128)	17.11.2018 – 16.11.2019
Meloxoral (EMEA/V/C/000151)	19.11.2018 – 18.11.2019
Oxyglobin (EMEA/V/C/000045)	29.11.2018 – 28.11.2019
Porcilis AR-T DF (EMEA/V/C/000055)	16.11.2018 – 15.11.2019
Quadrisol (EMEA/V/C/000032)	04.12.2018 – 03.12.2019
Rabitec (EMEA/V/C/004387)	01.12.2018 – 30.11.2019
Stronghold (EMEA/V/C/000050)	25.11.2018 – 24.11.2019
Vectra 3D (EMEA/V/C/002555)	04.12.2018 – 03.12.2019

5.4 Renewals

- No items

5.5 Pharmacovigilance - PSURs and SARs

• **Advocate** EMEA/V/C/000076	Rapp: T.-M. Muhonen ***For adoption:*** CVMP assessment report on the PSUR for the period 01.05.2016-30.04.2019
• **Coliprotec F4/F18** EMEA/V/C/004225	Rapp: E. Augustynowicz ***For endorsement***: Rapporteur's evaluation on the PSUR for the period 01.02.2019-31.07.2019
• **NexGard Spectra** EMEA/V/C/003842	Rapp: J. G. Beechinor ***For endorsement:*** Rapporteur's evaluation on the PSUR for the period 01.08.1208-31.07.2019

• **Rheumocam** EMEA/V/C/000121	Rapp: S. Louet ***For endorsement:*** Rapporteur's assessment report on the PSUR for the period 01.08.2016-31.07.2019
• **UBAC** EMEA/V/C/004595	Rapp: E. Werner ***For endorsement:*** Rapporteur's assessment report on the PSUR for the period 01.02.2019-31.07.2019
• **Versican Plus DHPPi** EMEA/V/C/003679	Rapp: E. Werner ***For endorsement:*** Rapporteur's assessment report on the PSUR for the period 01.08.18-31.07.19
• **Versican Plus DHPPi L4R** EMEA/V/C/002759	Rapp: E. Werner ***For endorsement:*** Rapporteur's assessment report on the PSUR for the period 01.06.2018-31.05.2019
• **Versican Plus L4** EMEA/V/C/003680	Rapp: E. Werner ***For endorsement:*** Rapporteur's assessment report on the PSUR for the period 01.08.2018-31.07.2019
• **Versican Plus Pi** EMEA/V/C/003681	Rapp: E. Werner ***For endorsement:*** Rapporteur's assessment report on the PSUR for the period 01.08.2018-31.07.2019
• **Versican Plus Pi L4** EMEA/V/C/003683	Rapp: E. Werner ***For endorsement:*** Rapporteur's assessment report on the PSUR for the period 01.08.2018-31.07.2019
• **Versican Plus Pi L4R** EMEA/V/C/003682	Rapp: E. Werner ***For endorsement:*** Rapporteur's assessment report on the PSUR for the period 01.08.2018-31.07.2019

- ***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 adoption***: VICH GL58 Stability Testing of New Veterinary Drug Substances and Medicinal Products in Climatic Zones III and IV for implementation at step 7
- ***For information***: Feedback on 37th VICH Steering Committee and Outreach Forum meetings held from 18 – 21 November 2019

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 relating to SAWP-V procedures and 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)

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

8.3 Antimicrobial resistance

- ***For adoption:*** Updated scientific advice on the AMEG categorisation of antibiotics in the European Union; overview of comments
- ***For information***: Verbal report on the 9th European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) report on sales of veterinary antimicrobial agents in 31 European countries in 2017

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 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

- ***For decision:*** Transfer of (co-)rapporteurship responsibilities from W. Schlumbohm to G. Hahn

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***: Verbal report from the CMDv chair on the meetings held on 10-11 October and 7-8 November 2019; draft minutes of the 7-8 November 2019 meeting; draft agenda of the meeting to be held on 5-6 December 2019

12. ORGANISATIONAL AND STRATEGIC MATTERS

- ***For adoption***: CVMP work plan 2020
- ***For information:*** Update on relocation to EMA permanent building
- ***For information:*** Agenda of the post-public consultation veterinary stakeholders' workshop to be held on 5-6 December 2019 at the EMA, Amsterdam

13. LEGISLATION

- ***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 signal detection and adverse events and pharmacovigilance inspections and pharmacovigilance system master file; on pharmacovigilance communication; on format for the collection of data for antimicrobials used in animals; on rules for oral administration of veterinary medicinal products; and, on 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
Dec 2019	3-5								3		
Jan 2020	21-23						21-22		21		
Feb 2020	18-19								18		
Mar 2020	17-19						24-25		17		