



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 June 2020
EMA/321774/2020 draft 3
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Draft agenda of June 2020 meeting

Chair: D. Murphy

Vice-chair: G. J. Schefferlie

16 June 2020, 09:00 – 18 June 2020, 13:00 – Adobe Connect (virtual)

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 or minutes cannot be released at present within the framework of Regulation (EC) No 1049/2001 on access to documents because they are subject to ongoing 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 | N/a |
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1. ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS

1.1 Opinions

- **Substance**
EMA/V/MRL/005009/FULL/0002
Bovine
For adoption: CVMP opinion including EPMAR, CVMP assessment report
For information: Summary of opinion

1.2 Oral explanations and list of outstanding issues

- **Substance**
EMA/V/MRL/003649/EXTN/0002
Porcine
ORAL EXPLANATION – Wednesday, 17 June 2020 at 10:50 CET
For discussion: Rapporteurs' assessment report of responses to list of outstanding issues

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 Opinions

- No items

2.2 Oral explanations and list of outstanding issues

- **Product**
EMA/V/C/005180/0000
New product
Dogs
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

- **Product**
EMA/V/C/5354/0000
New product
Dogs
For adoption: Scientific overview and list of questions, comments on product information
- **Product**
EMA/V/C/005482/0000
New vaccine
Chickens
For adoption: CVMP scientific overview and list of questions, comments on the product information

- **Aivlosin**
EMA/V/C/000083/X/0081
To add new target species
Rapp: C. Bergman
Co-rapp: A. Golombiewski
For adoption: CVMP scientific overview and list of questions, comments on the product information

2.4 Re-examination of CVMP opinions

- No items

2.5 Other issues

- No items

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

- **Bluevac BTV8**
EMA/V/C/000156/II/0010/G
To convert the Bluevac BTV8 dossier into a multi-strain dossier
Rapp: E. Werner
Co-rapp: P. Pasquali
For adoption: CVMP opinion, CVMP assessment report, product information
For information: Summary opinion
- **Stronghold Plus and Felisecto Plus**
EMA/V/C/xxxxxx/WS1828
To amend the product information
Rapp: R. Breathnach
For adoption: CVMP opinion
For endorsement: Rapporteur's assessment report

3.2 Oral explanations and list of outstanding issues

- **Nobilis IB Primo QX**
EMA/V/C/002802/II/0008
To amend the product information due to new safety data
Rapp: C. Miras
For adoption: List of outstanding issues, comments on product information
- **UpCard**
EMA/V/C/003836/II/0005/G
Quality-related changes
Rapp: C. Muñoz Madero
For adoption: Second list of outstanding issues

3.3 List of questions

- **Innovax-ND-IBD**
EMA/V/C/004422/II/0004
To extend the duration of immunity
Rapp: J. Poot
Co-rapp: E. Werner
For adoption: List of questions, comments on product information
- **Advocate**
EMA/V/C/000076/II/0043
To update the SPC in light of safety data
Rapp: T.-M. Muhonen
For adoption: List of questions, comments on product information

- **Simparica Trio** Rapp: R. Breathnach
 EMEA/V/C/004846/II/0001
Quality-related changes **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

- **Dinolytic 12.5 mg/ml and 5 mg/ml solutions for injection and associated names, and generic products thereof** Rapp: S. Louet
 EMEA/V/A/136
Withdrawal periods Co-rapp: G. J. Schefferlie
For adoption: CVMP opinion, CVMP assessment report
- **Stresnil 40 mg/ml solution for injection for pigs and associated names, and generic products thereof** Rapp: A. Golombiewski
 EMEA/V/A/138
Withdrawal periods Co-rapp: L. Nepejchalová
For discussion: Rapporteur's assessment report including co-rapporteur's critique
- **Valbazen 100 mg/ml Spectrum Wormer oral suspension and associated names, including its generic/hybrid products** Rapp: A. Golombiewski
 EMEA/V/A/140
Withdrawal periods Co-rapp: J. G. Beechinor
For decision: Need for outstanding issues
For discussion: Rapporteur's assessment report including co-rapporteur's critique
- **Betamox LA 150 mg/ml suspension for injection and its associated names, and generics products thereof** Rapp: A. Golombiewski
 EMEA/V/A/132
Withdrawal periods Co-rapp: P. Hekman
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

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

- Suvaxyn PRRS MLV**
EMA/V/C/004276/REC/012
Recommendation
Rapp: E. Werner
Co-rapp: F. Klein
For endorsement: Rapporteur's assessment report
- Fortekor Plus**
EMA/V/C/002804/REC/019
Recommendation
Rapp: N. C. Kyvsgaard
Co-rapp: C. Muñoz Madero
For endorsement: Rapporteur's assessment report

5.3 Product anniversary list

| Product | Period |
|---|-------------------------|
| Dany's BienenWohl (EMA/V/C/004667) | 14.06.2019 – 13.06.2020 |
| Equilis West Nile (EMA/V/C/002241) | 06.06.2019 – 05.06.2020 |
| Leucogen (EMA/V/C/000144) | 17.06.2019 – 16.06.2020 |
| MS-H Vaccine (EMA/V/C/000161) | 14.06.2019 – 13.06.2020 |
| Nobilis IB 4-91 (EMA/V/C/000036) | 09.06.2019 – 08.06.2020 |
| Porcilis ColiClos (EMA/V/C/002011) | 14.06.2019 – 13.06.2020 |
| Porcilis Pesti (EMA/V/C/000046) | 09.06.2019 – 08.06.2020 |

| Product | Period |
|---|-------------------------|
| Poulvac E. coli (EMA/V/C/002007) | 15.06.2019 – 14.06.2020 |
| Sileo (EMA/V/C/003764) | 10.06.2019 – 09.06.2020 |
| Vectra Felis (EMA/V/C/002746) | 06.06.2019 – 05.06.2020 |

5.4 Renewals

- Suvaxyn Circo + MH RTU**
EMA/V/C/003924/R/0015

Rapp: B. Urbain
Co-rapp: M. Blixenkroner-Møller

For adoption: List of outstanding issues
- Zycortal**
EMA/V/C/003782/R/0006

Rapp: H. Bergendahl
Co-rapp: J. P. Duarte Da Silva

For adoption: CVMP opinion, CVMP assessment report, product information
- Simparica**
EMA/V/C/003991/R/0018

Rapp: J. G. Beechinor
Co-rapp: P. Hekman

For adoption: CVMP opinion, CVMP assessment report, product information

5.5 Pharmacovigilance - PSURs and SARs

- Purevax FeLV**
EMA/V/C/000056

Rapp: B. Urbain

For adoption: CVMP assessment report on the PSUR for the period 01.11.2016-31.10.2019
- Vectra 3D**
EMA/V/C/002555

Rapp: A. Golombiewski

For adoption: CVMP assessment report on the PSUR for the period 01.07.2018-30.12.2019
- Comfortis**
EMA/V/C/000056

Rapp: A. Golombiewski

For endorsement: Rapporteur assessment report on the PSUR for the period 01.10.2016-30.09.2019
- Credelio**
EMA/V/C/004247

Rapp: R. Breathnach

For endorsement: Rapporteur assessment report on the PSUR for the period 01.08.2019-31.01.2020
- Innovax ILT**
EMA/V/C/003869

Rapp: E. Werner

For endorsement: Rapporteur assessment report on the PSUR for the period 01.02.2019-31.01.2020
- Masivet**
EMA/V/C/000128

Rapp: A. Golombiewski

For endorsement: Rapporteur assessment report on the PSUR for the period 01.12.2016-30.11.2019

- **Melovem**
 EMEA/V/C/000152

Rapp: R. Breathnach

For endorsement: Rapporteur assessment report on the PSUR for the period 01.02.2017-31.01.2020
- **Nasym**
 EMEA/V/C/004897

Rapp: J. G. Beechinor

For endorsement: Rapporteur assessment report on the PSUR for the period 29.07.2019-31.01.2020
- **Osurnia**
 EMEA/V/C/003753

Rapp: S. Louet

For endorsement: Rapporteur assessment report on the PSUR for the period 01.02.2019-31.01.2020
- **ProZinc**
 EMEA/V/C/002634

Rapp: R. Breathnach

For endorsement: Rapporteur evaluation on the PSUR for the period 01.08.2017-31.01.2020
- **Sileo**
 EMEA/V/C/003764

Rapp: F. Hasslung Wikström

For endorsement: Rapporteur assessment report on the PSUR for the period 01.01.2019-31.12.2019
- **Ubac**
 EMEA/V/C/004595

Rapp: E. Werner

For endorsement: Rapporteur assessment report on the PSUR for the period 01.08.2019-31.01.2020
- **Zactran**
 EMEA/V/C/000129

Rapp: N. C. Kyvsgaard

For endorsement: Rapporteur evaluation on the PSUR for the period 01.02.2019-31.01.2020
- **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

6.2 Codex Alimentarius

- No items

6.3 Other EU bodies and international organisations

- **For discussion:** Letter from the Secretariat of the European Pharmacopoeia Commission regarding the Ph. Eur. text soon to cover GMO and novel vaccines
- **For information:** Call for members of the WHO Strategic and Technical Advisory Group for Antimicrobial Resistance (STAG-AMR) – see also 8.3

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 adoption:** Draft CVMP strategy on antimicrobials 2021-2025
- **For information:** Call for members of the WHO Strategic and Technical Advisory Group for Antimicrobial Resistance (STAG-AMR)– see also 6.3
- **For information:** Publication of the AMEG infographic translations

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:** Verbal report from the CMDv chair on the meetings held on 23 April and 19-20 May 2020; draft minutes of the 19-20 May 2020 meeting; draft agenda of the meeting held on 18-19 June 2020

12. ORGANISATIONAL AND STRATEGIC MATTERS

- **For information:** Verbal report from the chair of the Strategic Planning Group (SPG) on the meeting held on 15 June 2020; draft agenda of the meeting; draft minutes of the April 2020 meeting

13. LEGISLATION

- **For adoption:** Scientific recommendations for implementing measures under Article 57(4) of Regulation (EU) 2019/6 on veterinary medicinal products regarding the format of the data to be collected on antimicrobial medicinal products used in animals
- **For information:** Verbal update on work progress of the expert group concerning provision of scientific recommendations on implementing act to Regulation (EU) 2019/6 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 |
|------------------|-------------|---------------|------------|--------------|------------|------------|--------------|------------|-------------|------------|--------------------|
| Jun 2020 | 16-18 | | | | | | | | | | |
| Jul 2020 | 14-16 | | | | | | 7-8 | | 14 | | |
| Sept 2020 | 8-10 | | | | | | 22-23 | 16-18 | 10 | | |
| Oct 2020 | 6-8 | | | | | | | | 6 | | |
| Nov 2020 | 3-5 | | | | | | 24-25 | | 3 | | |