15 January 2021
EMA/32304/2021 draft 3
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Draft agenda of January 2021 meeting

Chair: D. Murphy

Vice-chair: G. J. Schefferlie

19 January 2021, 09:00 – 21 January 2021, 13:00 - 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/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)	Monday, 18 January 2021	13:00-16:00 CET

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

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/MLR/003802/MODF/0002
  Fin fish
  ***For decision*:** Request for an extension of the clock-stop

2. COMMUNITY MARKETING AUTHORISATIONS AND EXTENSIONS

2.1 Opinions

- No items

2.2 Oral explanations and list of outstanding issues

- No items

2.3 List of questions

- No items

2.4 Re-examination of CVMP opinions

- No items

2.5 Other issues

- **Product**
  EMEA/V/C/005132/0000
  New product
  Dogs
  For decision: Request for an extension of the clock-stop
- ***For endorsement:*** EPAR scientific discussion for **Librela** (EMEA/V/C/005180/0000)
- ***For endorsement:*** EPAR scientific discussion for **Innovax -ND-ILT** (EMEA/V/C/005190/0000)
- ***For endorsement:*** EPAR scientific discussion for **PREVEXXION RN+HVT+IBD** (EMEA/V/C/005057/0000)
- ***For endorsement:*** EPAR scientific discussion for **PREVEXXION RN** (EMEA/V/C/005058/0000)
- ***For endorsement:*** EPAR scientific discussion for **Rexxolide** (EMEA/V/C/005384/0000)

- ***For endorsement:*** EPAR scientific discussion for **NexGard Combo** (EMEA/V/C/005094/0000)

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

- **Exzolt**
  EMEA/V/C/004344/II/0011
  To amend the product information
  Rapp: K. Boerkamp
  For adoption: CVMP opinion, CVMP assessment report, product information

- **Nobilis IB Primo QX**
  EMEA/V/C/002802/II/0009/G
  Quality-related changes
  Rapp: C. Miras
  For adoption: CVMP opinion, product information
  For endorsement: Rapporteur's assessment report

- **Nobilis IB 4-91**
  EMEA/V/C/000036/II/0027/G
  Quality-related changes
  Rapp: C. Miras
  For adoption: CVMP opinion, product information
  For endorsement: Rapporteur's assessment report

- **Eravac**
  EMEA/V/C/004239/II/0006
  Quality-related changes
  Rapp: C. Muñoz Madero
  For adoption: CVMP opinion, product information
  For endorsement: Rapporteur's assessment report

- **Melosus**
  EMEA/V/C/002001/II/0012
  Quality-related changes
  Rapp: N. C. Kyvsgaard
  For adoption: CVMP opinion
  For endorsement: Rapporteur's assessment report

- **Meloxoral**
  EMEA/V/C/000151/II/0011
  Quality-related changes
  Rapp: A. Golombiewski
  For adoption: CVMP opinion
  For endorsement: Rapporteur's assessment report

- **Cytopoint**
  EMEA/V/C/003939/II/0011/G
  Quality-related changes
  Rapp: R. Breathnach
  For adoption: CVMP opinion
  For endorsement: Rapporteur's assessment report

- **VarroMed**
  EMEA/V/C/002723/II/0004/G
  Quality-related changes
  Rapp: K. Štraus
  For adoption: CVMP opinion
  For endorsement: Rapporteur's assessment report

3.2 Oral explanations and list of outstanding issues

- **Cortavance**
  EMEA/V/C/000110/II/0015
  To add a new therapeutic indication
  Rapp: N. C. Kyvsgaard
  Co-rapp: C. Muñoz Madero
  For adoption: List of outstanding issues

- **Gumbohatch**
  EMEA/V/C/004967/II/0004
  Quality-related changes

  Rapp: J. G. Beechinor

  For adoption: List of outstanding issues

3.3 List of questions

- **Porcilis ColiClos**
  EMEA/V/C/002011/II/0012
  Quality-related changes

  Rapp: E. Werner

  For adoption: List of questions

3.4 Re-examination of CVMP opinions

- No items

3.5 Other issues

- **Simparica Trio**
  EMEA/V/C/004846/II/0001
  Quality-related changes

  Rapp: R. Breathnach

  For decision: Request for an extension of the clock stop

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

- **Ronaxan and its associated names** (doxycycline)
  EMEA/V/A/135
  Harmonisation of SPC

  Rapp: F. Hasslung Wikström

  Co-rapp: J. G. Beechinor

  For decision: Need for list of outstanding issues

  For discussion: Rapporteur's assessment report including co-rapporteur's critique, draft product information

4.3 Article 35 of Directive 2001/82/EC

- **Modified live porcine respiratory and reproductive syndrome (PRRS) virus vaccines**
  EMEA/V/A/142
  Animal health

  Rapp: E. Werner

  Co-rapp: F. Klein

  For adoption: List of questions to the *Ad Hoc* Expert Group (AHEG)

  For endorsement: Composition of the AHEG

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

Information on certain topics discussed under section 4.7 cannot be released at the present time as it is deemed to be confidential

- 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**
Bovela (EMEA/V/C/003703)	22.12.2019 – 21.12.2020
BTVPUR (EMEA/V/C/002231)	17.12.2019 – 16.12.2020
Cepedex (EMEA/V/C/004376)	13.12.2019 – 12.12.2020
Halagon (EMEA/V/C/004201)	13.12.2019 – 12.12.2020
Onsior (EMEA/V/C/000127)	16.12.2019 – 16.12.2020
Prac-tic (EMEA/V/C/000103)	18.12.2019 – 17.12.2020
SevoFlo (EMEA/V/C/000072)	11.12.2019 – 10.12.2020
Activyl Tick Plus (EMEA/V/C/002234)	09.01.2020 – 08.01.2021
Coliprotec F4/F18 (EMEA/V/C/004225)	09.01.2020 – 08.01.2021
Cortavance (EMEA/V/C/000110)	09.01.2020 – 08.01.2021
Galliprant (EMEA/V/C/004222)	09.01.2020 – 08.01.2021
Isemid (EMEA/V/C/004345)	09.01.2020 – 08.01.2021
Meloxidyl (EMEA/V/C/000115)	15.01.2020 – 14.01.2021
Metacam (EMEA/V/C/000033)	07.01.2020 – 06.01.2021
NexGard Spectra (EMEA/V/C/003842)	15.01.2020 – 14.01.2021
Porcilis PCV (EMEA/V/C/000135)	12.01.2020 – 11.01.2021
Respiporc FLU3 (EMEA/V/C/000153)	14.01.2020 – 13.01.2021

Product	Period
Rheumocam (EMEA/V/C/000121)	10.01.2020 – 09.01.2021
Stelfonta (EMEA/V/C/005018)	15.01.2020 – 14.01.2021
Syvazul BTV (EMEA/V/C/004611)	09.01.2020 – 08.01.2021
Ypozane (EMEA/V/C/000112)	11.01.2020 – 10.01.2021
Zulvac 8 Ovis (EMEA/V/C/000147)	15.01.2020 – 14.01.2021

5.4 Renewals

- **Sevohale**
  EMEA/V/C/004199/R/0007

  Rapp: J. G. Beechinor

  Co-rapp: J. Hederová

  For adoption: List of outstanding issues

5.5 Pharmacovigilance - PSURs and SARs

- **Evant**
  EMEA/V/C/004902

  Rapp: J. G. Beechinor

  For endorsement: Rapporteur assessment report on the PSUR for the period 01.03.2020-31.08.2020

- **Pirsue**
  EMEA/V/C/000054

  Rapp: A. Golombiewski

  For endorsement: Rapporteur assessment report on the PSUR for the period 01.08.2017-31.07.2020

- **Respiporc FLU3**
  EMEA/V/C/000153

  Rapp: M. Blixenkrone-Møller

  For endorsement: Rapporteur assessment report on the PSUR for the period 01.08.2018-31.07.2020

- **Semintra**
  EMEA/V/C/002436

  Rapp: R. Breathnach

  For endorsement: Rapporteur evaluation on the PSUR for the period 01.09.2019-31.08.2020

- **Stelfonta**
  EMEA/V/C/005018

  Rapp: K. Boerkamp

  For endorsement: Rapporteur assessment report on the PSUR for the period 15.01.2020-31.07.2020

- **Suvaxyn Circo**
  EMEA/V/C/004242

  Rapp: F. Klein

  For endorsement: Rapporteur assessment report on the PSUR for the period 01.03.2020-31.08.2020

- **Suvaxyn PCV**
  EMEA/V/C/000149 (WD)

  Rapp: B. Urbain

  For endorsement: Rapporteur assessment report on the PSUR for the period 01.08.2017-31.07.2020

- **VarroMed**
  EMEA/V/C/002723

  K. Štraus

  For endorsement: Rapporteur assessment report on the PSUR for the period 03.08.2019-02.08.2020

- ***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

- No items

6. CO-OPERATION WITH OTHER EU OR INTERNATIONAL BODIES

6.1 VICH

- ***For endorsement:*** Revision of VICH guidelines on efficacy of anthelmintics, draft EU comments on: GL7 (general) - Arithmetic/Geometric mean; GL7 (general) - Age of field isolates and laboratory strains; GL7 (general) - Adequacy of infection - statistical justification; GL12 (bovines), 13 (ovines), 14 (caprines), and 15 (equines) – Fecal egg count reduction tests; GL16 (porcines) - Ascaris suum L3 claims and Field studies; GL19 (canines) and 20 (felines) - Persistent efficacy; and GL21 (poultry) - Field studies
- ***For endorsement:*** Concept paper proposing development of VICH GLs to parallel ICH Q8 (Pharmaceutical Development), ICH Q9 (Quality Risk Management) and ICH Q10 (Pharmaceutical Quality System)

6.2 Codex Alimentarius

- No items

6.3 Other EU bodies and international organisations

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)

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 MRL 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

- No items

8.3 Antimicrobial resistance

- ***For adoption:*** CVMP strategy on antimicrobials for 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

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-)rapporteurships responsibilities from:

  - A. Askdal Bjelland to H. Bergendahl
  - K. Kivilahti-Mantyla to M. Leppänen

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 CMDv meetings held on 5-6 November 2020 and 3-4 December 2020; draft minutes of the 3-4 December 2020 meeting; draft agenda of the meeting to be held on 21-22 January 2021; draft agenda of the CMDv-Interested Parties meeting to be held on 22 January 2021

12. ORGANISATIONAL AND STRATEGIC MATTERS

- ***For adoption:*** CVMP work plan for 2021
- ***For information:*** Verbal report from the chair of the Strategic Planning Group on the meeting to be held on 15 January 2021 and agenda; minutes of the 29 October 2020 meeting
- ***To note:*** updated list of acronyms, abbreviations and capitalisations used in CVMP agenda and minutes (EMA/456228/2013-Rev. 1)

13. LEGISLATION

- ***For information:*** Commission Implementing Regulation (EU) 2021/17 of 8 January 2021 establishing a list of variations not requiring assessment and Commission Implementing Regulation (EU) 2021/16 of 8 January 2021 laying down the necessary measures and practical arrangements for the Union product database on veterinary medicinal products (link)

14. ANY OTHER BUSINESS

- ***For comments***: Meeting highlights

ANNEX

	CVMP	ADVENT	AWP	ERAWP	EWP	IWP	PhVWP	QWP	SAWP	SWP	J3Rs WG
Jan 2021	19-21								18		-
Feb 2021	16-18								15/16		-
Mar 2021	16-18		2-3		23-24		23-24	1-3	15/16		-
Apr 2021	13-15								12/13	22/23	-
May 2021	10-12		25-26			26-27	25-26	25-27	7		-