12 February 2021
EMA/CVMP/68573/2021 draft 3
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Draft agenda of February 2021 meeting

Chair: D. Murphy

Vice-chair: G. J. Schefferlie

16 February, 09:00 – 18 February, 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, 15 February 2021	10:00-13:00 CET

1. ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS

1.1 Opinions

- No items

1.2 Oral explanations and list of outstanding issues

- **Substance**
  EMEA/V/MRL/004828/EXTN/0002
  Chickens

  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

- **Substance**
  EMEA/V/MRL/005302/FULL/0001
  Horses

  For information: Letter of withdrawal of application

2. COMMUNITY MARKETING AUTHORISATIONS AND EXTENSIONS

2.1 Opinions

- **Product**
  EMEA/V/C/005325/0000
  New product
  Dogs

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

  For information:
  Summary of opinion

- **Product**
  EMEA/V/C/005354/0000
  New product
  Dogs

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

  For information:
  Summary of opinion

- **Product**
  EMEA/V/C/005347/0000
  New vaccine
  Chickens

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

  For information:
  Summary of opinion

- **Emdocam**
  EMEA/V/C/002283/X/0012
  To add a new strength and a new target species

  Rapp: J. G. Beechinor

  Co-rapp: C. Muñoz Madero

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

  For information:
  Summary of opinion

- **Emdocam**
  EMEA/V/C/002283/X/0013
  To add a new strength and new pharmaceutical form
  Horses

  Rapp: J. G. Beechinor

  Co-rapp: C. Muñoz Madero

  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/005301/0000
  New vaccine
  Rabbits

  For decision: Need for an oral explanation

  For adoption: CVMP scientific overview and list of outstanding issues

2.3 List of questions

- **Product**
  EMA/V/C/005606/0000
  New product
  Cattle, pigs, sheep

  For adoption: CVMP scientific overview and list of questions

- **Product**
  EMEA/V/C/005538/0000
  New vaccine
  Dogs

  For adoption: Scientific overview and list of questions

- **Apoquel**
  EMEA/V/C/002688/X/0019
  To add a new pharmaceutical form
  Dogs

  Rapp: R. Breathnach

  Co-rapp: N. C. Kyvsgaard

  For adoption: Scientific overview and list of questions

2.4 Re-examination of CVMP opinions

- No items

2.5 Other issues

- **Product**
  EMEA/V/C/005660/0000
  New product
  Dogs

  For information: Letter of withdrawal of the marketing authorisation application

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

- **Equioxx**
  EMEA/V/C/000142/II/0024
  To introduce a new pharmacovigilance system

  Rapp: J. G. Beechinor

  For adoption: CVMP opinion*;* CVMP assessment report

- **Zactran**
  EMEA/V/C/000129/II/0045
  Quality-related changes

  Rapp: N. C. Kyvsgaard

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

- **ProteqFlu-Te**
  EMEA/V/C/000074/II/0030/G
  Quality-related changes

  Rapp: C. Miras

  For adoption: CVMP opinion, product information

  For endorsement: Rapporteur's assessment report

- **Vectormune ND**
  EMEA/V/C/003829/WS1892
  Quality-related changes

  Rapp: F. Klein

  For adoption: CVMP opinion, product information

  For endorsement: Rapporteur's assessment report

- **Aivlosin**
  EMEA/V/C/000083/II/0085/G
  Quality-related changes

  Rapp: C. Bergman

  For adoption: CVMP opinion

  For endorsement: Rapporteur's assessment report

- **Suvaxyn CSF Marker**
  EMEA/V/C/002757/II/0008
  Quality-related changes

  Rapp: M. Blixenkrone-Møller

  For adoption: CVMP opinion

  For endorsement: Rapporteur's assessment report

- **Eurican Herpes 205**
  EMEA/V/C/000059/WS1971/0029
  Quality-related changes

  Rapp: J. G. Beechinor

  For adoption: CVMP opinion

  For endorsement: Rapporteur's assessment report

3.2 Oral explanations and list of outstanding issues

- No items

3.3 List of questions

- No items

3.4 Re-examination of CVMP opinions

- No items

3.5 Other issues

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

- No items

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

- **Zulvac SBV**
  EMEA/V/C/002781/REC/019
  Recommendation

  Rapp: G. Kulcsár

  Co-rapp: M. Blixenkrone-Møller

  For endorsement: Rapporteur's assessment report

5.3 Product anniversary list

Product	**Period**
Activyl (EMEA/V/C/000163)	18.02.2020 – 17.02.2021
Aservo EquiHaler (EMEA/V/C/004991)	28.01.2020 – 27.01.2021
Bravecto (EMEA/V/C/002526)	11.02.2020 – 10.02.2021
Cimalgex (EMEA/V/C/000162)	18.02.2020 – 17.02.2021
Comfortis (EMEA/V/C/002233)	11.02.2020 – 10.02.2021
Evant (EMEA/V/C/004902)	05.02.2020 – 04.02.2021
Fevaxyn Pentofel (EMEA/V/C/000030)	05.02.2020 – 04.02.2021
Hiprabovis IBR Marker Live (EMEA/V/C/000158)	27.01.2020 – 26.01.2021
Ingelvac CircoFLEX (EMEA/V/C/000126)	13.02.2020 – 12.02.2021
Kexxtone (EMEA/V/C/002235)	28.01.2020 – 27.01.2021
Kriptazen (EMEA/V/C/004868)	08.02.2020 – 07.02.2021
Loxicom (EMEA/V/C/000141)	10.02.2021 – 09.02.2021

Product	Period
MiPet Easecto (EMEA/V/C/004732)	31.01.2020 – 30.01.2021
NexGard (EMEA/V/C/002729)	11.02.2020 – 10.02.2021
Nobilis OR inac (EMEA/V/C/000062)	24.01.2020 – 23.01.2021
Oxybee (EMEA/V/C/004296)	01.02.2020 – 31.01.2021
Pirsue (EMEA/V/C/000054)	29.01.2020 – 28.01.2021
Purevax Rabies (EMEA/V/C/002003)	18.02.2020 – 17.02.2021
Semintra (EMEA/V/C/002436)	13.02.2020 – 12.02.2021
Startvac (EMEA/V/C/000130)	11.02.2020 – 10.02.2021
Stronghold Plus (EMEA/V/C/004194)	09.02.2020 – 08.02.2021
Suvaxyn Circo (EMEA/V/C/004242)	07.02.2020 – 06.02.2021
Suvaxyn CSF Marker (EMEA/V/C/002757)	10.02.2020 – 09.02.2021
VarroMed (EMEA/V/C/002723)	02.02.2020 – 01.02.2021
Zulvac SBV (EMEA/V/C/002781)	06.02.2020 – 05.02.2021

5.4 Renewals

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

  Rapp: J. G. Beechinor

  Co-rapp: J. Hederová

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

5.5 Pharmacovigilance - PSURs and SARs

- **Stronghold Plus** and **Felisecto Plus**
  EMEA/V/C/004194
  EMEA/V/C/005093

  Rapp: R. Breathnach

  For adoption: CVMP assessment report on the joint PSUR for the period 01.09.2019-31.08.2020

- **Aivlosin**
  EMEA/V/C/000083

  Rapp: C. Bergman

  For endorsement: Rapporteur assessment report on the PSUR for the period 01.10.2019-30.09.2020

- **Coliprotec F4/F18**
  EMEA/V/C/004225

  Rapp: E. Augustynowicz

  For endorsement: Rapporteur evaluation on the PSUR for the period 01.08.2019-31.07.2020

- **Cortacare**
  EMEA/V/C/004689

  Rapp: S. Louet

  For endorsement: Rapporteur assessment report on the PSUR for the period 01.11.2017-30.10.2020

- **Eurican Herpes 205**
  EMEA/V/C/000059
  Rapp: J. G. Beechinor
  For endorsement: Rapporteur evaluation on the PSUR for the period 01.10.2017-30.09.2020
- **Fortekor Plus**
  EMEA/V/C/002804
  Rapp: N. C. Kyvsgaard
  For endorsement: Rapporteur assessment report on the PSUR for the period 01.10.2019-30.09.2020
- **Leucofeligen FeLV RCP**
  EMEA/V/C/000143
  Rapp: E. Werner
  For endorsement: Rapporteur assessment report on the PSUR for the period 01.07.2017-30.06.2020
- **Pexion**
  EMEA/V/C/002543
  Rapp: S. Louet
  For endorsement: Rapporteur assessment report on the PSUR for the period 01.09.2017-31.08.2020

- ***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

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

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

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

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

- ***For adoption:*** Reflection paper on eligibility criteria for limited markets – *see also point 13*
- ***For adoption:*** Guideline on safety and residue data requirements for applications for non-immunological veterinary medicinal products intended for limited markets submitted under Article 23 of Regulation (EU) 2019/6; guideline on safety and residue data requirements for the establishment of Maximum Residue Limits in minor species; overview of comments received during the previous public consultation – *see also point 13*
- ***For adoption:*** Guideline on efficacy and target animal safety data requirements for applications for non-immunological veterinary medicinal products intended for limited markets submitted under Article 23 of the Regulation (EU) 2019/6 – *see also point 13*
- ***For adoption:*** Guideline on data requirements for applications for immunological veterinary medicinal products intended for limited markets applications submitted under Article 23 of the Regulation (EU) 2019/6 – *see also point 13*
- ***For endorsement:*** 11th Annual report on Veterinary MUMS/Limited market, for adoption by Management Board on 11 March 2021

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

- ***To note:*** Minutes of the 21-22 January 2021 CMDv meeting; agenda of the CMDv meeting to be held on 18-19 February 2021

12. ORGANISATIONAL AND STRATEGIC MATTERS

- ***For information:*** EMA/AnimalhealthEurope Info Day to be held on 25 March 2021
- ***For information:*** EU NTC Veterinary Training Coordination group activities

13. LEGISLATION

- ***For adoption:*** Reflection paper on eligibility criteria for limited markets – *see also point 9*
- ***For adoption:*** Guideline on safety and residue data requirements for applications for non-immunological veterinary medicinal products intended for limited markets submitted under Article 23 of Regulation (EU) 2019/6; guideline on safety and residue data requirements for the establishment of Maximum Residue Limits in minor species; overview of comments received during the previous public consultation – *see also point 9*
- ***For adoption:*** Guideline on efficacy and target animal safety data requirements for applications for non-immunological veterinary medicinal products intended for limited markets submitted under Article 23 of the Regulation (EU) 2019/6 – *see also point 9*
- ***For adoption:*** Guideline on data requirements for applications for immunological veterinary medicinal products intended for limited markets applications submitted under Article 23 of the Regulation (EU) 2019/6 – *see also point 9*

14. ANY OTHER BUSINESS

- ***For comments***: News highlights of the meeting

ANNEX

	CVMP	NTWP	AWP	ERAWP	EWP	IWP	PhVWP	QWP	SAWP	SWP	J3Rs WG
Feb 2021	16-18								15		-
Mar 2021	16-18		2-3	4-5	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		-
Jun 2021	15-17				1-2				14/15		