14 February 2020
EMA/82677/2020 draft 3
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Draft agenda of February 2020 meeting

Chair: D. Murphy

Vice-chair: G. J. Schefferlie

18 February 2020, 09:00 – 20 February 2020, 13:00 - Room 2C

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 2C)	Tuesday, 18 February 2020	16:30-20:00 (TBC)

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1. ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS

1.1 Opinions

• **Substance** EMEA/V/MRL/005009/FULL/0001 *Porcine*	***For adoption:*** CVMP opinion, CVMP assessment report ***For information:*** Summary of opinion

1.2 Oral explanations and list of outstanding issues

• **Substance** EMEA/V/MRL/003652/MODF/0003 *Bovine*	***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/004481/FULL/0002 *Salmonidae*	***For adoption:*** List of questions to the Ad Hoc Expert Group (AHEG) ***For discussion:*** Rapporteurs' assessment report ***For endorsement:*** Composition of the AHEG
• **Substance** EMEA/V/MRL/003649/EXTN/0002 *Porcine*	***For adoption:*** List of questions to the Ad Hoc Expert Group (AHEG) ***For discussion:*** Rapporteurs' assessment report ***For endorsement:*** Composition of the AHEG

2. COMMUNITY MARKETING AUTHORISATIONS AND EXTENSIONS

2.1 Opinions

• **Product** EMEA/V/C/005077/0000 *New vaccine* *Chickens*	***For adoption:*** CVMP opinion, CVMP assessment report, product information ***For information:*** Summary of opinion
• **Product** EMEA/V/C/005073/0000 *New product* *Cattle, pigs, sheep*	***For adoption:*** CVMP opinion, CVMP assessment report, product information ***For information:*** Summary of opinion
• **Product** EMEA/V/C/005153/0000 *New product* *Cattle, pigs, sheep*	***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/005149/0000 *New vaccine* *Pigs*	***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 EMEA/V/C/005364/0000 *New product* *Cattle, pigs, sheep*	***For adoption:*** Scientific overview and list of questions, comments on product information
• **Product** EMEA/V/C/005305/0000 *New product* *Cattle, pigs, sheep*	***For adoption:*** Scientific overview and list of questions, comments on product information

2.4 Re-examination of CVMP opinions

- No items

2.5 Other issues

• **Product** EMEA/V/C/005301/0000 *New vaccine* *Rabbits*	***For adoption:*** Request from applicant to extend the clock-stop

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

• **CLYNAV** EMEA/V/C/002390/II/0010 *To extend the duration of immunity*	Rapp: J. G. Beechinor **ORAL EXPLANATION – Tuesday 18 February 2020, 14:30-15:30** ***For discussion:*** Rapporteurs' assessment of responses to list of outstanding issues, product information ***For adoption:*** CVMP opinion, CVMP assessment report, product information ***For information:*** Summary of opinion
• **Porcilis PCV M Hyo** EMEA/V/C/003796/WS1717/0013 *To modify the product information*	Rapp: E. Werner ***For adoption:*** CVMP opinion, CVMP assessment report, product information
• **Bravecto, Exzolt** and **Bravecto Plus** EMEA/V/C/xxxxxx/WS1764 *To implement quality-related changes*	Rapp: P. Hekman ***For adoption:*** CVMP opinion ***For endorsement:*** Rapporteur's assessment report

• **Vaxxitek HVT+IBD** EMEA/V/C/xxxxxx/WS1763 *To implement quality-related changes*	Rapp: B. Urbain ***For adoption:*** CVMP opinion ***For endorsement:*** Rapporteur's assessment report
• **Panacur AquaSol** EMEA/V/C/002008/II/0017 *To implement quality-related changes*	Rapp: G. J. Schefferlie ***For adoption:*** CVMP opinion ***For endorsement*:** Rapporteur's assessment report
• **Imrestor** EMEA/V/C/002763/II/0012 *To implement quality-related changes*	Rapp: N. C. Kyvsgaard ***For adoption:*** CVMP opinion ***For endorsement:*** Rapporteur's assessment report
• **Evicto** EMEA/V/C/004973/II/0001 *To implement 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

• **Zulvac BTV** EMEA/V/C/004185/II/0004 *To vary the existing multi-strain dossier*	Rapp: F. Klein Co-rapp: P. Pasquali ***For adoption***: List of questions, comments on product information
• **Aivlosin** EMEA/V/C/000083/II/0080/G *To implement quality-related changes*	Rapp: F. Hasslung Wikström ***For adoption*:** List of questions
• **Posatex** EMEA/V/C/000122/II/0028/G *To implement quality-related changes*	Rapp: S. Louet ***For adoption:*** List of questions
• **Purevax RCPCh FeLV, Purevax FeLV, Purevax RCP FeLV** EMEA/V/C/xxxxx/WS1733/G *To implement quality-related changes*	Rapp: B. Urbain ***For adoption:*** List of questions, comments on the product information
• **Purevax RC, Purevax RCP, Purevax RCPCH** EMEA/V/C/xxxxx/WS1732/G *To implement quality-related changes*	Rapp: B. Urbain ***For adoption:*** List of questions, comments on the product information

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

• **Valbazen 100 mg/ml Spectrum Wormer oral suspension and associated names, and generic products (including hybrid generic products) thereof** EMEA/V/A/140 *Withdrawal periods*	Rapp: *to be appointed* Co-rapp: *to be appointed* ***For discussion and decision***: Notification from Germany under Article 35 of Directive 2001/82/EC Appointment of rapporteur, co-rapporteur and peer reviewers

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

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** EMEA/V/C/004276/REC/011 *Recommendation*	Rapp: E. Werner Co-rapp: F. Klein ***For endorsement:*** Rapporteur's assessment report

5.3 Product anniversary list

Product	Period
Activyl (EMEA/V/C/000163)	18/02/2019 – 17/02/2020
Bravecto (EMEA/V/C/002526)	11/02/2019 – 10/02/2020
Cimalgex (EMEA/V/C/000162)	18/02/2019 – 17/02/2020
Comfortis (EMEA/V/C/002233)	11/02/2019 – 10/02/2020
Evant (EMEA/V/C/004902)	05/02/2019 – 04/02/2020
Fevaxyn Pentofel (EMEA/V/C/000030)	05/02/2019 – 04/02/2020
Hiprabovis IBR Marker Live (EMEA/V/C/000158)	27/01/2019 – 26/01/2020
Ingelvac CircoFLEX (EMEA/V/C/000126)	13/02/2019 – 12/02/2020
Kexxtone (EMEA/V/C/002235)	28/01/2019 – 27/01/2020
Kriptazen (EMEA/V/C/004868)	08/02/2019 – 07/02/2020
Loxicom (EMEA/V/C/000141)	10/02/2019 – 09/02/2020
MiPet Easecto (EMEA/V/C/004732)	31/01/2019 – 20/01/2020
NexGard (EMEA/V/C/002729)	11/02/2019 – 10/02/2020
Nobilis OR inac (EMEA/V/C/000062)	24/01/2019 – 23/01/2020
Oxybee (EMEA/V/C/004296)	01/02/2019 – 31/01/2020
Pirsue (EMEA/V/C/000054)	29/01/2019 – 28/01/2020
Purevax Rabies (EMEA/V/C/002003)	18/02/2019 – 17/02/2020
Semintra (EMEA/V/C/002436)	13/02/2019 - 12/02/2020
Startvac (EMEA/V/C/000130)	11/02/2019 – 10/02/2020
Stronghold Plus (EMEA/V/C/004194)	09/02/2019 – 08/02/2020
Suvaxyn Circo (EMEA/V/C/004242)	07/02/2019 – 06/02/2020
Suvaxyn CSF Marker (EMEA/V/C/002757)	10/02/2019 – 09/02/2020
VarroMed (EMEA/V/C/002723)	02/02/2019 – 01/02/2020
Zulvac SBV (EMEA/V/C/002781)	06/02/2019 – 05/02/2020

5.4 Renewals

• **Canigen L4** EMEA/V/C/004079/R/0007	Rapp: B. Urbain Co-rapp: R. Breathnach ***For adoption:*** CVMP opinion, CVMP assessment report, product information
• **Sileo** EMEA/V/C/003764/R/0014	Rapp: F. Hasslung Wikström Co-rapp: J. G. Beechinor ***For adoption:*** CVMP opinion, CVMP assessment report, product information
• **Innovax ILT** EMEA/V/C/003869/R/0005	Rapp: E. Werner Co-rapp: L. Nepejchalová ***For adoption:*** CVMP opinion, CVMP assessment report, product information
• **UpCard** EMEA/V/C/003836/R/0004	Rapp: C. Muñoz Madero Co-rapp: J. G. Beechinor ***For adoption:*** List of outstanding issues

5.5 Pharmacovigilance - PSURs and SARs

• **Arti-Cell Forte** EMEA/V/C/004727	Rapp: F. Hasslung Wikström ***For endorsement:*** Rapporteur's assessment report on the PSUR for the period 29.03.2019-30.09.2019
• **Forceris** EMEA/V/C/004329	Rapp: C. Muñoz Madero ***For endorsement:*** Rapporteur's assessment report on the PSUR for the period 23.04.2019-30.09.2019
• **Fortekor Plus** EMEA/V/C/0028804	Rapp: N. C. Kyvsgaard ***For endorsement:*** Rapporteur's assessment report on the PSUR for the period 01.10.2018-30.09.2019
• **Imrestor** EMEA/V/C/002763	Rapp: N. C. Kyvsgaard ***For endorsement:*** Rapporteur's assessment report on the PSUR for the period 01.10.2018-30.09.2019
• **Incurin** EMEA/V/C/000047	Rapp: P. Pasquali ***For endorsement:*** Rapporteur's assessment report on the PSUR for the period 01.10.2016-30.08.2019
• **Previcox** EMEA/V/C/000082	Rapp: J. G. Beechinor ***For endorsement:*** Rapporteur's assessment report on the PSUR for the period 29.03.2019-30.09.2019

• **Suvaxyn PRRS MLV** EMEA/V/C/004276	Rapp: E. Werner ***For endorsement:*** Rapporteur's assessment report on the PSUR for the period 01.03.2019-31.08.2019

- ***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 endorsement:*** VICH GL23 on genotoxicity – proposed EU response to chair's request
- ***For endorsement:*** VICH GL22 on reproduction toxicity testing – proposed EU comments in response to kick-off message from the EWG Chair following adoption of concept paper for revision of the guideline
- ***For discussion:*** Nomination of adviser for development of a VICH guideline for safety evaluation of biotechnology-derived/biological products
- ***For discussion:*** Call for nomination of adviser to work on development of a discussion document on signal detection and signal management
- ***For information:*** Revision of VICH anthelmintic guidelines: Draft EU comments on:
  - Arithmetic and Geometric Means (dose confirmation studies)
  - VICH GL 7 (general) - Age of Field Isolates and Laboratory Strains
  - VICH GL 7 - Adequacy of infection - Statistical Justification
  - VICH GL 12, 13 ,14, 15, 19, 20 - Adequacy of Infection/Helminth numbers
  - VICH GL 12 (bovine), 13 (ovine), 14 (caprine), 15 (equine) – Faecal egg count reduction test
  - VICH GL16 (porcine) – Claims for Ascaris suum L3 larvae
  - VICH GL 19-20 (cats, dogs) - Persistent efficacy
  - CVMP statistical essential points
- ***For information:*** Need for new EU experts to join VICH safety and metabolism and residues kinetics EWGs

6.2 Codex Alimentarius

- No items

6.3 Other EU bodies and international organisations

- No items

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

- No items

8.3 Antimicrobial resistance

Information on certain topics discussed under section 8.3 cannot be released at the present time as it is deemed to be confidential

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:

  - F. Hasslung Wikström and E. Lander Persson to C. Bergman
  - J.-C. Rouby to C. Miras
  - G. Hahn to E. Werner

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 23-24 January 2020 meeting; draft agenda of the meeting to be held on 20-21 February 2020

12. ORGANISATIONAL AND STRATEGIC MATTERS

- ***For information:*** Verbal report from the chair of the Strategic Planning Group (SPG) on the meeting to be held on 19 February 2020; draft agenda of the meeting; draft minutes of the November 2019 meeting
- ***For information:*** Upcoming informal presidency CVMP-CMDv meeting (to be held during the Croatian EU Presidency) to be held on 4-5 June 2020 at Maisons-Alfort, France
- ***For information:*** Minutes of the meeting between veterinary training coordination group and curriculum leads held on 23 January 2020
- ***To note:*** 3rd international awareness session on science and regulation for animal health and welfare, public health and the environment to take place in 2-3 April 2020 at the EMA (link); programme overview (link)
- ***To note:*** Veterinary Info Day and CVMP Interested Parties' meeting to take place on 18-19 June 2020 at the EMA

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; and on rules for oral administration of veterinary medicinal products; on list of antimicrobials reserved for the treatment of certain infections in humans

- ***For information:*** Draft mandate from the Commission for the expert group to deliver the scientific recommendations on Implementing measures of Regulation (EU) 2019/6 regarding the establishment of a list of antimicrobials, which shall not be used in accordance with Articles 112, 113 and 114 or which shall be used in accordance with these articles subject to certain conditions
- ***For information:*** Verbal report from the CVMP chair on the 'Expectations of the Annex 2 proposal of Regulation 2019/6' meeting held on 6-7 February 2020 at Munich, Germany

14. ANY OTHER BUSINESS

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

ANNEX

	CVMP	ADVENT	AWP	ERAWP	EWP	IWP	PhVWP	QWP	SAWP	SWP	J3Rs WG
Feb 2020	18-20							4-6	18		
Mar 2020	17-19						24-25		17		
Apr 2020	21-23								21		
May 2020	18-20						12-13	12-14	18		
Jun 2020	16-18				9-10				16		