7 November 2017
EMA/CVMP/750093/2017
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Minutes of the October 2017 meeting

Chair: D. Murphy – Vice-chair: H. Jukes

Note on access to documents

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

The Committee adopted the agenda with no modifications.

ii. CVMP delegates' list of intended participation and identified interests

The attendance list was completed and competing interests were identified for the October 2017 meeting. In accordance with the Agency's policy and procedure on the handling of competing interests, participants in this meeting were 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 took 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 the meeting (see Annex I). All decisions taken at this meeting were made in presence of a quorum of members i.e. 22 or more members were present in the room. It was noted that 17 members were needed for an absolute majority.

iii. Declaration of contacts between members and companies with regard to points on the agenda

Information relating to declared contacts between members and companies with regard to points on the agenda cannot be released at the present time as it is deemed to be commercially confidential.

No contacts were declared.

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iv. Adoption of the minutes of the previous meeting

The minutes of the September 2017 meeting were adopted with no amendments.

v. Topics for rapporteur's meetings, break-out sessions and oral explanations

Information relating to briefing meetings taking place with applicants cannot be released at the present time as it is deemed to be commercially confidential.

1. ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS

1.1 Opinions

- The Committee adopted by majority (26 members in favour out of the 28 members present of those eligible to vote) the CVMP opinion including the EPMAR and the CVMP assessment report recommending the extension of MRLs to fin fish for **fluazuron** (EMEA/V/MRL/003471/EXTN/0002). Furthermore, the Committee agreed to extrapolate the established MRLs for fluazuron in bovine species to tissues of all ruminants except ovine species and to milk of bovine species. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP. G. Kulcsár and L. Nepejchalová presented a divergent position not supporting the aforementioned recommendation. The Committee noted the report from the EU Reference Laboratory, a peer review report, the comments received from CVMP members and the summary of opinion for publication.
- The Committee adopted by consensus (26 members present of those eligible to vote) the CVMP opinion including the EPMAR and the CVMP assessment report recommending the establishment of MRLs in all food producing species for **solvent naphtha, light aromatic** (EMEA/V/MRL/004321/FULL/0001). The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP. The Committee noted the comments received from CVMP members and the summary of opinion for publication.

1.2 Oral explanations and lists of outstanding issues

- There were no items for discussion.

1.3 Lists of questions

- The Committee discussed the draft rapporteur's EPMAR, a peer review report and the report from the EU Reference Laboratory for the extension of MRLs to fin fish for a substance (EMEA/V/MRL/003141/EXTN/0004), and agreed that a list of questions was not necessary. The adoption of the opinion is foreseen for the November 2017 meeting of the Committee.
- The Committee adopted the scientific overview and list of questions for the establishment of MRLs in chickens for a substance (EMEA/V/MRL/004856/FULL/0001), following discussion of the rapporteur's assessment report including the critique from the co-rapporteur and of two peer review reports.

1.4 Re-examination of CVMP opinions

- There were no items for discussion.

1.5 Other issues

- The Committee was informed of the formal notification from the applicant of their decision to withdraw the application for the establishment of MRLs in honey for a substance (EMEA/V/MRL/003596/FULL/0002).

2. COMMUNITY MARKETING AUTHORISATIONS AND EXTENSIONS

2.1 Opinions

- The Committee adopted by consensus (27 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **Rabitec** (EMEA/V/C/004387/0000), recommending the granting of a marketing authorisation. The product is a new live attenuated rabies vaccine for oral use in foxes and raccoon dogs. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP. The Committee noted the summary of opinion for publication.

- The Committee adopted by consensus (26 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **MiPet Easecto** (EMEA/V/C/004732/0000), recommending the granting of a marketing authorisation. MiPet Easecto is a new antiparasitic product for the treatment of tick infestations, flea infestations, sarcoptic mange, ear mites and demodicosis in dogs. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP. The Committee noted the summary of opinion for publication.

2.2 Oral explanations and lists of outstanding issues

- The Committee adopted the updated scientific overview including the list of outstanding issues and agreed comments on the draft product information for a marketing authorisation application for a new product (EMEA/V/C/004417/0000). The Committee agreed that an oral explanation would not be requested, and noted two peer review reports and the comments received from CVMP members.

- The Committee heard an oral explanation from the applicant concerning an application for a new anti-inflammatory product for dogs (EMEA/V/C/004222/0000). The Committee also discussed the draft product information and the rapporteurs' assessment of the responses to the list of outstanding issues. The adoption of the opinion is foreseen for the November 2017 CVMP meeting.

2.3 Lists of questions

- The Committee adopted the scientific overview including the list of questions and agreed comments on the draft product information for a new anti-inflammatory product for dogs (EMEA/V/C/004689/0000). The Committee noted a peer review report and the comments received from CVMP members.

- The Committee adopted the scientific overview including the list of questions and agreed comments on the draft product information for an extension application for **Credelio** (EMEA/V/C/004485/X/0001), to add a new strength for a new target species. The Committee noted two peer review reports and the comments received from CVMP members.

- The Committee adopted the scientific overview including the list of questions and agreed comments on the draft product information for an extension application for **Semintra** (EMEA/V/C/002436/X/0008), to add a new strength and a new indication. The Committee noted two peer review reports and the comments received from CVMP members.

- The Committee adopted the scientific overview including the list of questions, and agreed comments on the draft product information for an extension application for **Rheumocam** (EMEA/V/C/000121/X/0022), to add a new pharmaceutical form and strength. The Committee noted a peer review report and the comments received from CVMP members.

- The Committee adopted the scientific overview including the list of questions, and agreed comments on the draft product information for an extension application for **Inflacam** (EMEA/V/C/002497/X/0015), to add a new pharmaceutical form and strength. The Committee noted a peer review report and the comments received from CVMP members.

2.4 Re-examination of CVMP opinions

- There were no items for discussion.

2.5 Other issues

- The Committee agreed to the request from the applicant for an extension to the clock-stop for a new product for musculo-skeletal disorders in dogs (EMEA/V/C/004375/0000).
- The Committee endorsed the EPAR module 6 scientific discussion for **Exzolt** (EMEA/V/C/004344/0000) concerning the granting of the initial marketing authorisation.
- The Committee endorsed the EPAR module 6 scientific discussion for **Nobivac LeuFel** (EMEA/V/C/004778/0000) concerning the granting of the initial marketing authorisation.

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

- The Committee adopted by consensus (26 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for a type II variation for **SevoFlo** (EMEA/V/C/000072/II/0020), recommending the variation of the marketing authorisation to add a new target species (cats). The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted by consensus (26 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for a grouped type II variation for **Porcilis PCV M Hyo** (EMEA/V/C/003796/II/0006/G), recommending the variation of the marketing authorisation to implement quality changes and changes to the SPC and package leaflet. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted by consensus (26 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for a type II variation for **Imrestor** (EMEA/V/C/002763/II/0005), recommending the variation of the marketing authorisation to implement quality changes. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted by consensus (26 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for a type II variation for **Hiprabovis IBR Marker Live** (EMEA/V/C/000158/II/0009), recommending the variation of the marketing authorisation to implement quality changes. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.

3.2 Oral explanations and lists of outstanding issues

- There were no items for discussion.

3.3 Lists of questions

- The Committee adopted the rapporteur's assessment report including the list of questions and agreed comments on the product information for a type II variation for **Vectormune ND** (EMEA/V/C/003829/II/0007), to add a new target species.
- The Committee adopted the rapporteur's assessment report including the list of questions for a type II variation for **Panacur AquaSol** (EMEA/V/C/002008/II/0015), to add a new therapeutic indication.
- The Committee adopted the rapporteur's assessment report including the list of questions for a type II variation for **Onsior** (EMEA/V/C/000127/II/0018), to add a new therapeutic indication.
- The Committee adopted the rapporteur's assessment report including the list of questions for a grouped type II variation for **Meloxidyl** (EMEA/V/C/000115/II/0023/G), concerning quality changes.
- The Committee adopted the rapporteur's assessment report including the list of questions for a worksharing type II variation for **Oncept IL2**, **Parvoduk**, **ProteqFlu**, **Proteq West Nile**, **ProteqFlu Te**, **Purevax FeLV**, **Purevax Rabies**, **Purevax RC**, **Purevac RCP**, **Purevax RCP FeLV**, **Pu8revax RCPCh**, **Purevax RCPCh FeLV** and **Vaxxitek HVT+IBD** (EMEA/V/C/xxxxxx/WS/1195), concerning quality changes.

3.4 Re-examination of CVMP opinions

- There were no items for discussion.

3.5 Other issues

- The Committee agreed to a request from the MAH for an extension to the clock-stop for a type II variation for **Metacam** (EMEA/V/C/000033/II/0127), to register an additional target species.

4. REFERRALS AND RELATED PROCEDURES

4.1 Article 33 of Directive 2001/82/EC

- There were no items for discussion.

4.2 Article 34 of Directive 2001/82/EC

- The Committee adopted by majority (23 members in favour out of the 28 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for the referral procedure for **Girolan and its associated name Apralan** (EMEA/V/A/122), recommending the harmonisation of the product information for the concerned products. K. Baptiste, K. Lehmann, L. Nepejchalová, E.-M. Vestergaard and E. Kozhuharov presented divergent positions. The Norwegian CVMP member supported one of the divergent positions.

4.3 Article 35 of Directive 2001/82/EC

- The Committee discussed the rapporteur's assessment of the responses to the list of questions and the revised rapporteur's assessment report for the follow-up assessment for the referral procedure for **veterinary medicinal products containing enrofloxacin to be administered via the drinking water to chickens and/or turkeys** (EMEA/V/A/089). The Committee agreed to the request from a marketing authorisation holder, Bayer Animal Health, to provide an oral explanation. The Committee adopted a list of questions for the marketing authorisation holder to address at the oral explanation and the revised timetable for the procedure.

4.4 Article 78 of Directive 2001/82/EC

- There were no items for discussion.

4.5 Article 13 of Regulation (EC) No 1234/2008

- There were no items for discussion.

4.6 Article 30(3) of Regulation (EC) No 726/2004

- There were no items for discussion.

4.7 Other issues

- There were no items for discussion.

The following documents were circulated for information:

- Questions and answers for publication on veterinary medicinal products containing moxidectin to be administered to cattle, sheep and horses following an Article 35 referral (EMEA/V/A/116);
- Questions and answers for publication on Lincocin and its associated names – Article 34 referral (EMEA/V/A/123);
- Questions and answers for publication on Zanil and its associated names, and generic products thereof – Article 35 referral (EMEA/V/A/124).

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

5.1 General issues

- There were no items for discussion.

5.2 Post-authorisation measures and annual reassessments

- The Committee endorsed the rapporteur's assessment report on the data submitted concerning a recommendation for **Coliprotec F4/F18** (EMEA/V/C/004225/REC/008).

5.3 Product anniversary list

- The Committee endorsed the product anniversary list for the period between 08.09.2017 – 05.10.2017:

Product	Period
Aivlosin (EMEA/V/C/000083)	09/09/2016 – 08/09/2017
APOQUEL (EMEA/V/C/002688)	12/09/2016 – 11/09/2017
Cerenia (EMEA/V/C/000106)	29/09/2016 – 28/09/2017
COXEVAC (EMEA/V/C/000155)	30/09/2016 – 29/09/2017
ERAVAC (EMEA/V/C/004239)	22/09/2016 – 21/09/2017
FORTEKOR PLUS (EMEA/V/C/002804)	08/09/2016 – 07/09/2017
Nobivac Bb (EMEA/V/C/000068)	10/09/2016 – 09/09/2017
Novaquin (EMEA/V/C/003866)	08/09/2016 – 07/09/2017

Product	Period
Palladia (EMEA/V/C/000150)	23/09/2016 – 22/09/2017
Previcox (EMEA/V/C/000082)	13/09/2016 – 12/09/2017
Recocam (EMEA/V/C/002247)	13/09/2016 – 12/09/2017
RHINISENG (EMEA/V/C/000160)	16/09/2016 – 15/09/2017
Trifexis (EMEA/V/C/002635)	19/09/2016 – 18/09/2017
Trocoxil (EMEA/V/C/000132)	09/09/2016 – 09/09/2017
Vectormune ND (EMEA/V/C/003829)	08/09/2016 – 07/09/2017

5.4 Renewals

- The Committee adopted by consensus (26 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for the renewal of the marketing authorisation for **Pexion** (EMEA/V/C/002543/R/0010), and recommended that the authorisation should now be indefinite. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted by consensus (28 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for the renewal of the marketing authorisation for **Kexxtone** (EMEA/V/C/002235/R/0009), and recommended that the authorisation should now be indefinite. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted the list of outstanding issues and discussed the product information for the renewal of the marketing authorisation for **Semintra** (EMEA/V/C/002436/R/0009).

5.5 Pharmacovigilance – PSURs and SARs

- The Committee discussed the CVMP assessment report of the PSUR for **Bravecto** (EMEA/V/C/002526) for the period 01.09.2016 – 28.02.2017 with a recommendation to amend the product information of Bravecto spot-on solution.
- The Committee endorsed the following rapporteurs' assessment reports on PSURs concluding that no changes to the product literature or other regulatory actions were required for:

Product	Period
Apoquel (EMEA/V/C/002688)	01.12.2016 – 31.05.2017
DRAXXIN (EMEA/V/C/000077)	01.12.2016 – 31.05.2017
Fungitraxx (EMEA/V/C/002722)	01.10.2016 – 31.03.2017
Imrestor (EMEA/V/C/002763)	01.10.2016 – 31.03.2017
Porcilis PCV M Hyo (EMEA/V/C/003865)	01.12.2016 – 31.05.2017
ProMeris (WD) (EMEA/V/C/000107)	01.06.2014 – 31.05.2017
ProMeris Duo (WD) (EMEA/V/C/000108)	01.06.2014 – 31.05.2017
Simparica (EMEA/V/C/003991)	01.12.2016 – 31.05.2017

Suvaxyn Circo MH RTU (EMEA/V/C/003924)	01.12.2016 – 31.05.2017
Versican Plus DHPPi L4 (EMEA/V/C/003678)	02.12.2016 – 31.05.2017
Versican Plus DHPPi L4R (EMEA/V/C/002759)	02.12.2016 – 31.05.2017
Zycortal (EMEA/V/C/003782)	01.12.2016 – 31.05.2017

- The Committee endorsed the list of products and calendar for signal detection analysis.

5.6 Supervision and sanctions

Information relating to supervision and sanctions will not be published as it would be undermining the purpose of such inspections.

The following document was circulated for information:

- Status report on PSURs for centrally authorised veterinary medicinal products.

6. CO-OPERATION WITH OTHER EU OR INTERNATIONAL BODIES

6.1 VICH

- The Committee noted the draft agenda of the 35th VICH Steering Committee meeting to be held on 13-17 November 2017 in Tokyo and the draft agenda of the 9th VICH Outreach Forum meeting to be held on 14-15 November 2017 in Tokyo.
- The Committee endorsed the EU comments on the draft VICH guideline on stability studies for climatic zones III and IV.

6.2 Codex Alimentarius

- The Committee discussed the proposed draft revision of the code of practice to minimise and contain antimicrobial resistance (CAC/RCP 61-2005), and the proposed draft guidelines for the integrated [monitoring and] surveillance of foodborne antimicrobial resistance CL 2017/82-AMR, further to the request of the European Commission – *see also 8.3*.

6.3 Other EU bodies and international organisations

- The Committee was informed of the opinion adopted by ECHA proposing harmonised classification and labelling for Vitamin D3 (colecalciferol).

The following document was circulated for information:

- Status of active VICH guidelines and action plan of CVMP and working parties.

7. WORKING PARTIES AND SCIENTIFIC ADVISORY GROUPS

Information relating to certain topics discussed under section 7 at this meeting 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-V procedures cannot be released at the present time as it is deemed to be commercially confidential.

- The Committee received a verbal report from the chair of the SAWP-V on the meeting held on 3 October 2017, and noted the agenda of the meeting.

7.2 Quality Working Party (QWP)

- The Committee received a verbal report from the veterinary vice-chair of the QWP on the meeting held on 27-29 September 2017, and noted the agenda of the meeting, and also the agenda of the Joint QWP/GMDP IWG meeting held on 27 September 2017.
- The Committee adopted the guidance for the phased implementation of requirements to control elemental impurities in veterinary medicinal products.
- The Committee was informed of the comments from the Process Analytical Technology (PAT) team on the FDA public consultation on the best practices document on continuous manufacturing.
- The Committee noted the questions and answers on elemental impurities in veterinary medicinal products.

7.3 Safety Working Party (SWP-V)

- The Committee deferred the verbal report from the chair of the SWP-V on the meeting held on 20 September 2017 to the November 2017 CVMP meeting.
- The Committee discussed the overview of comments received during the public consultation on the guideline on assessment and control of DNA reactive (mutagenic) impurities in veterinary medicinal products, and agreed for SWP-V to proceed with the revision of the guideline.
- The Committee discussed the overview of comments received during the public consultation on the guideline on assessing the toxicological risk to human health and the environment from veterinary pharmaceuticals in groundwater, and agreed for the ERAWP and SWP to proceed with the revision of the guideline - *see also 7.4*.

7.4 Environmental Risk Assessment Working Party (ERAWP)

- The Committee discussed the development of the higher tier testing of veterinary medicines on dung fauna following the stakeholders' workshop held in June 2017.
- The Committee discussed the overview of comments received during the public consultation on the guideline on assessing the toxicological risk to human health and the environment from veterinary pharmaceuticals in groundwater, and agreed for the ERAWP and the SWP to proceed with the revision of the guideline - *see also 7.3*.

7.5 Efficacy Working Party (EWP-V)

- The Committee received a verbal report from the chair of the EWP-V on the meeting held on 12-13 September 2017, and noted the agenda of the meeting.
- The Committee discussed the draft revised guideline on the conduct of pharmacokinetic studies in target animals, which is foreseen to be adopted at the November 2017 CVMP meeting.
- The Committee discussed the concept paper for the revision of the guideline on the summary of product characteristics for anthelmintics, which is foreseen to be adopted at the November 2017 CVMP meeting.

7.6 Antimicrobials Working Party (AWP)

- The Committee deferred the verbal report from the chair of the AWP on the meeting held on 20-21 September 2017 to the November 2017 CVMP meeting.

7.7 Immunologicals Working Party (IWP)

- There were no items for discussion.

7.8 Pharmacovigilance Working Party (PhVWP-V)

- The Committee received a verbal report from the vice-chair of the PhVWP-V on the meeting held on 26-27 September 2017, and noted the agenda of the meeting.
- The Committee endorsed the mandate to the PhVWP-V for continued work on the methodology and targeted analysis of adverse event data related to anti-parasitics.
- The Committee discussed the revised recommendation for the basic surveillance of EudraVigilance Veterinary data and the comments received during the consultation period from IFAH Europe, and agreed to mandate the PhVWP-V to finalise the recommendation.
- The Committee elected Els Dewaele as chair of the PhVWP-v for a 3-year term.
- The Committee received a verbal report from the PhVWP-V interested parties meeting held on 27 September 2017, and noted the agenda of the meeting.

7.9 Novel therapy groups and related issues

- The Committee discussed the questions and answers on stem cell-based products for veterinary use, focusing on specific questions on tumorigenicity, which are foreseen to be adopted at the November 2017 CVMP meeting.

7.10 Joint CVMP/CHMP Working Group on the application of the 3Rs (J3RsWG)

- The Committee endorsed the participation of a J3RsWG expert at the meeting of the Preliminary Assessment of Regulatory Relevance (PARERE) network and the joint meeting of the PARERE and the ECVAM Stakeholder Forum (ESTAF) networks, to be held on 27-29 November 2017 at the European Commission Joint Research Centre in Ispra, Italy. The invitation and the draft agenda of the meeting were noted.

7.11 Other working party and scientific group issues

- The Committee deferred the discussion of the draft work plans of the CVMP working parties for 2018 to the November 2017 CVMP meeting.

The following documents were circulated for information:

- Minutes of the SAWP-V meeting held on 5 September 2017;
- Minutes of the EWP-V meeting held on 30-31 May 2017;
- Draft agenda of the IWP meeting to be held on 18-19 October 2017;
- Draft minutes of the IWP meeting held on 21-22 June 2017, final agenda of the meeting;
- Minutes of the ADVENT meeting held on 15 June 2017.

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

- There were no items for discussion.

8.3 Antimicrobial resistance

- The Committee received a verbal report on the new AMEG mandate, and discussed the draft action plan, the draft timetable and the composition of the AMEG. The new AMEG is foreseen to include representation from CVMP/AWP, CHMP/IDWP, ECDC, EFSA, JIACRA and EURL-AR, corresponding to 10 members. The AMEG composition will be agreed at the November 2017 meeting.
- The Committee discussed the proposed draft revision of the Code of practice to minimise and contain antimicrobial resistance (CAC/RCP 61-2005), and the proposed draft guidelines for the integrated [monitoring and] surveillance of foodborne antimicrobial resistance CL 2017/82-AMR, further to the request of the European Commission – *see also 6.2*.

8.4 Pharmacovigilance

- There were no items for discussion.

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 contain commercially confidential information.

- The Committee noted the written feedback on the European Association of Fish Pathologists (EAFP) 18th International Conference on fish and shellfish diseases held on 4-8 September 2017 in Belfast, Northern Ireland, and noted the programme of the conference.

The following documents were circulated for information:

- Joint ECDC, EFSA and EMA scientific opinion on a list of outcome indicators as regards surveillance of antimicrobial resistance and antimicrobial consumption in humans and food-producing animals.

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.

- The Committee was informed of the comments received from IFAH-Europe on the draft final report of the focus group meeting with invited stakeholders on field efficacy trial requirements for the authorisation of veterinary vaccines in the EU, held on 22-23 June 2017. The comments will be discussed at the next meeting of the EMA/HMA Steering Group for vaccine availability, and the final report is foreseen to be endorsed for release for publication by CVMP at their November 2017 meeting.

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.

- The Committee agreed to the transfer of the co-rapporteurship for **Zeleris** from L. Markus Cizelj to F. Bozic.
- The Committee agreed to the transfer of the rapporteurship for **Oxybee** from G. J. Schefferlie to J. Poot.

10.2 Regulatory matters

Information relating to certain topics discussed under 10.2 cannot be released at the present time as it is deemed to be confidential.

11. CO-ORDINATION GROUP FOR MUTUAL RECOGNITION AND DECENTRALISED PROCEDURES

- The Committee received a verbal report from the chair of CMDv on the meeting held on 7-8 September 2017 and noted the draft minutes of the meeting as well as the draft agenda of the meeting held on 5-6 October 2017.

12. ORGANISATIONAL AND STRATEGIC MATTERS

- The Committee received a verbal report from the chair of the Strategic Planning Group on the meeting held on 4 October 2017, and noted the agenda of the meeting and the minutes of the meeting held on 12 July 2017.
- The Committee was informed of the adopted best practice guide on measures improving predictability of submissions/responses and adherence to communicated submission/responses deadlines, and the related overview of comments.

13. LEGISLATION

Information relating to certain legislative issues cannot be released at the present time as it is deemed to be confidential

14. ANY OTHER BUSINESS

- Upon the completion of the October 2017 CVMP meeting, the draft press release was circulated for members to provide any comments within 24 hours.

ANNEX I - List of participants including any restrictions with respect to involvement of members / alternates / experts following evaluation of declared interests for the October 2017 meeting

Country	CVMP Member	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
CHAIR	**David Murphy**	**Full involvement**	
BE	Bruno Urbain	Full involvement	
BG	Emil Kozhuharov	Full involvement	
CY	Alia Michaelidou	Full involvement	
DE	Gesine Hahn	Full involvement	
DK	Ellen-Margrethe Vestergaard	Full involvement	
EE	Toomas Tiirats	Full involvement	
EL	Ioannis Malemis	Full involvement	
ES	Cristina Muñoz Madero	Full involvement	
FR	Jean-Claude Rouby	Full involvement	
HR	Frane Božić	Involvement in discussions only and cannot act as rapporteur or peer reviewer for:	• 4.3 enrofloxacin • 8.1 one item
HU	Gábor Kulcsár	Full involvement	
IE	J. Gabriel Beechinor	Full involvement	
LV	Zanda Auce	Full involvement	
NL	Peter Hekman	Full involvement	
PL	Anna Wachnik-Święcicka	Involvement in discussions only and cannot act as rapporteur or peer reviewer for:	• 4.3 enrofloxacin
RO	Lollita Taban	Full involvement	
SE	Eva Lander Persson	Full involvement	
SI	Katarina Straus	Full involvement	
UK	Helen Jukes	Full involvement	
Co-opted	Keith Baptiste	Full involvement	
Co-opted	Rory Breathnach	Full involvement	
Co-opted	G. Johan Schefferlie	Full involvement	
Co-opted	Wilhelm Schlumbohm	Full involvement	
Co-opted	Jason Weeks	Full involvement	
NO	Hanne Bergendahl	Full involvement	

Country	CVMP Alternate	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
AT	Petra Falb	Full involvement	
BE	Frédéric Klein	Full involvement	
CZ	Leona Nepejchalová	Full involvement	

Country	CVMP Alternate	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
DE	Esther Werner	Full involvement	
ES	Consuelo Rubio Montejano	Involvement in discussions only and cannot act as rapporteur or peer reviewer for:	• 2.5 Exzolt • 3.1 Porcilis PCV M Hyo • 3.3 Panacur AquaSol • 5.5 PSURs for Bravecto and Porcilis PCV M Hyo
FI	Kristina Lehmann	Full involvement	
FR	Sylvie Louet	Full involvement	
LT	Laimis Jodkonis	Full involvement	
NL	Jacqueline Poot	Full involvement	
SE	Frida Hasslung Wikström	Full involvement	
UK	Noemi Garcia del Blanco	Full involvement	

Country	CVMP Expert*	Outcome restriction following evaluation of the e-DoI for the meeting	Topics on current agenda for which restriction applies
* Experts were only evaluated against the topics they have been invited to talk about.			
BE	Sandy Vermout – *remotely*	Full involvement	
DE	Anke Finnah	Full involvement	
DK	Anne Engelbrecht Thomsen – *remotely*	Full involvement	
DK	Christian Friis	Full involvement	
DK	Lotte Gam Kristensen – *remotely*	Full involvement	
DK	John Jensen - *remotely*	Full involvement	
DK	Niels Kyvsgaard	Full involvement	
ES	Lucia Bans – *remotely*	Full involvement	
ES	Mercedes Conradi – *remotely*	Full involvement	
ES	Maria Dominguez – *remotely*	Full involvement	
ES	Aranzazu Gonzalez – *remotely*	Full involvement	
ES	Amparo Lopez – *remotely*	Full involvement	
ES	Gloria Montes – *remotely*	Full involvement	
ES	Patricia Vera – *remotely*	Full involvement	
FI	Martti Nevalainen – *remotely*	Full involvement	
FR	Elisabeth Begon – *remotely*	Full involvement	
FR	Benoit Courty – *remotely*	Full involvement	
FR	Lise Laborieux – *remotely*	Full involvement	

Country	CVMP Expert*	Outcome restriction following evaluation of the e-DoI for the meeting	Topics on current agenda for which restriction applies
FR	Laetitia Le Letty	Full involvement	
FR	Karen Millet – *remotely*	Full involvement	
IE	Mary O'Grady – *remotely*	Full involvement	
NL	Kim Boerkamp – *remotely*	Full involvement	
NL	Rico Slingerland	Full involvement	
UK	John Mitchell	Full involvement	

CVMP working parties and CMDv	Chair
ADVENT	Jean-Claude Rouby
AWP	Helen Jukes
CMDv	Laetitia Le Letty
ERAWP	Jason Weeks
EWP-V	Cristina Munoz Madero
IWP	Esther Werner
PhVWP-V	Elisabeth Begon *(vice chair) - remotely*
QWP	Mary O'Grady *(Vet vice chair) - remotely*
SAWP-V	Rory Breathnach
SWP-V	Eva Lander Persson

Observer from the European Commission	
Present	

Observers from Swissmedic	
Remotely	

European Medicines Agency support
Meeting run with relevant support from the EMA staff