12 July 2016
EMA/CVMP/476383/2016
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Minutes of the 14-16 June 2016 meeting

Chair: D. Murphy – Vice-chair: *vacant*

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 interests were identified for the June 2016 meeting. In accordance with the Agency's policy and procedure on the handling of declarations of 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 Scientific Committee members and, where relevant, experts attending the plenary meeting, as announced by the Scientific Committee 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.

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No contacts were declared.

iv. Adoption of the minutes of the previous meeting

The minutes of the May 2016 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

- There were no items for discussion.

1.2 Oral explanations and lists of outstanding issues

- There were no items for discussion.

1.3 Lists of questions

- There were no items for discussion.

1.4 Re-examination of CVMP opinions

- There were no items for discussion.

1.5 Other issues

- The Committee agreed to the request from the applicant for an extension to the clock-stop for the establishment of MRLs in porcine species for a substance (EMEA/V/MRL/004113/FULL/0001).
- The Committee agreed to the request from the applicant for an extension to the clock-stop for the establishment of MRLs in all food producing species for a substance (EMEA/V/MRL/004321/FULL/0001).

2. COMMUNITY MARKETING AUTHORISATIONS AND EXTENSIONS

2.1 Opinions

- 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 generic product **Sedadex** (EMEA/V/C/004202/0000), recommending the granting of a marketing authorisation. The product is for psycholeptic use in the form of solution for injection containing dexmedetomidine hydrochloride, for sedation and analgesia of dogs and cats. The Icelandic 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 (28 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **Metacam** (EMEA/V/C/000033/X/0119), recommending the extension of the marketing authorisation to add a new route of administration (subcutaneous use) for the 40mg/ml solution for injection in cattle. The Icelandic 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 and benefit-risk assessment 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/004201/0000), an antiparasitic product for cattle. The Committee agreed that an oral explanation would not be requested, and noted a peer review report.

2.3 Lists of questions

- The Committee adopted the scientific overview and benefit-risk assessment including the list of questions and agreed comments on the draft product information for a new antiparasitic product for cats (EMEA/V/C/004194/0000). The Committee noted two peer review reports and the comments received from CVMP members.
- The Committee adopted the scientific overview and benefit-risk assessment including the list of questions and agreed comments on the draft product information for a new analgesic product for cats (EMEA/V/C/004293/0000). The Committee noted two peer review reports and the comments received from CVMP members.
- The Committee adopted the scientific overview and benefit-risk assessment including the list of questions and agreed comments on the draft product information for a new anti-inflammatory product for dogs (EMEA/V/C/004222/0000). The Committee noted two peer review reports and the comments received from CVMP members.
- The Committee adopted the scientific overview and benefit-risk assessment including the list of questions and agreed comments on the draft product information for a new dermatological product for dogs (EMEA/V/C/003939/0000). The Committee noted two peer review reports and the comments received from CVMP members.

2.4 Re-examination of CVMP opinions

- The Committee agreed to the request from the applicant for the re-examination, in accordance with Regulation (EC) No 726/2004, of the CVMP opinion adopted for an extension application for **DRAXXIN** (EMEA/V/C/000077/X/0029), to add a new target species (sheep) to the solution for injection for cattle and pigs, and appointed a rapporteur and a co-rapporteur for the procedure. The Committee also agreed to the applicant's request for the involvement of an ad hoc expert group (AHEG). The submission of the detailed grounds for the re-examination is foreseen by 11 July 2016. The adoption of the opinion is foreseen for the September 2016 meeting of the Committee.

2.5 Other issues

- The Committee endorsed the EPAR module 6 scientific discussion for **Bravecto** (EMEA/V/C/002526/X/0005) concerning the extension of the marketing authorisation.
- The Committee endorsed the EPAR module 6 scientific discussion for **Sevocalm** (EMEA/V/C/004199/X/0005) concerning the granting of the initial marketing authorisation.

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

- There were no items for discussion.

3.2 Oral explanations and lists of outstanding issues

- The Committee adopted the list of outstanding issues to be addressed in writing and at an oral explanation for a type II variation for **Trifexis** (EMEA/V/C/002635/II/0008), to add a new therapeutic indication.

3.3 Lists of questions

- The Committee adopted the list of questions for a type II variation for **Activyl Tick Plus** (EMEA/V/C/002234/II/0008), to add a new therapeutic indication.
- The Committee adopted the list of questions for a type II variation for **Bravecto** (EMEA/V/C/002526/II/0011), to add wording to the SPC.
- The Committee adopted the list of questions for a type II variation for **Draxxin** (EMEA/V/C/000077/II/0035), to add wording to the SPC.

3.4 Re-examination of CVMP opinions

- There were no items for discussion.

3.5 Other issues

- There were no items for discussion.

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 discussed the rapporteur's assessment report including the co-rapporteur's critique for the referral procedure for **Denagard 45% and associated names** (EMEA/V/A/114). The Committee adopted the list of outstanding issues for the marketing authorisation holders to address in writing and the revised timetable for the procedure. The Committee noted two peer review reports and the comments made by CVMP members.

4.3 Article 35 of Directive 2001/82/EC

- The Committee discussed the rapporteur's assessment report including the co-rapporteur's critique for the referral procedure for **veterinary medicinal products containing moxidectin to be administered to cattle, sheep and horses** (EMEA/V/A/116). The Committee adopted the list of outstanding issues for the applicants and marketing authorisation holders to address in writing and the revised timetable for the procedure. The Committee noted two peer review reports and the comments made by CVMP members.
- The Committee discussed the rapporteur's assessment report including the co-rapporteur's critique for the referral procedure for **veterinary medicinal products containing gentamicin presented as solutions for injection to be administered to cattle and pigs** (EMEA/V/A/117). The Committee adopted the list of outstanding issues for the applicants and marketing authorisation holders to address in writing and the revised timetable for the procedure. The Committee noted three peer review reports and the comments made by CVMP members.

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

- The Committee considered a request from the European Commission to launch a procedure under Article 45 of Regulation 726/2004 for the centrally authorised product **Velactis** due to potential serious animal health concerns. The Committee agreed to the start of a procedure under Article 45 and appointed a rapporteur, a co-rapporteur and peer reviewers for the procedure. The Committee endorsed a 30-day timetable and a list of questions to the marketing authorisation holder. An opinion is foreseen for the July 2016 meeting – *see also 5.5.*

The following document was circulated for information:

- CattleMarker IBR Inactivated emulsion for injection for cattle - Article 33(4) referral (EMEA/V/A/115) – Questions and answers for publication

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

- There were no items for discussion.

5.3 Product anniversary list

- The Committee endorsed the product anniversary list for the period between 20.05.2016 – 16.06.2016:

Product	Period
Equilis West Nile (EMEA/V/C/002241)	06/06/2015 – 05/06/2016
MS-H Vaccine (EMEA/V/C/000161)	14/06/2015 – 13/06/2016
Nobilis IB 4-91 (EMEA/V/C/000036)	09/06/2015 – 08/06/2016
Porcilis ColiClos (EMEA/V/C/002011)	14/06/2015 – 13/06/2016
Porcilis Pesti (EMEA/V/C/000046)	09/06/2015 – 08/06/2016
Poulvac E. coli (EMEA/V/C/002007)	15/06/2015 – 14/06/2016
Sileo (EMEA/V/C/003764)	10/06/2015 – 09/06/2016
Vectra Felis (EMEA/V/C/002746)	06/06/2015 – 05/06/2016

5.4 Renewals

- 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 **Panacur AquaSol** (EMEA/V/C/002008/R/0011), and recommended that the authorisation should now be indefinite. The Icelandic CVMP member agreed with the above-mentioned recommendation of the CVMP.

5.5 Pharmacovigilance – PSURs and SARs

- The Committee adopted the CVMP assessment report of the final study report on a post-authorisation safety study (PASS) for **Trifexis** (EMEA/V/C/002635).
- The Committee discussed the adverse events including deaths and recumbency reported for **Velactis** (EMEA/V/C/003739) following a letter from CEVA Sante Animale and expressed concerns with the number of reports and severity of the adverse events occurring in a short period of time. The concerns were communicated to the European Commission. The Committee endorsed the need for urgent information on the matter to be provided to veterinarians. A draft "Direct veterinary surgeon communication" (EMA/CVMP/421150/2016) was circulated and members were requested to provide comments within 24 hours after the end of the meeting. – *see also 4.7.*
- The Committee adopted the CVMP assessment report of the PSUR for the period 01.07.2015-31.12.2015 for **Broadline** (EMEA/V/C/002700) with a recommendation to change the product information.
- The Committee adopted the CVMP assessment report of the PSUR for the period 01.02.2015-31.01.2016 for **Cardalis** (EMEA/V/C/002524) with a recommendation to change the product information.
- The Committee adopted the following CVMP PSUR assessment reports concluding that no changes to the product literature or other regulatory actions were required for:

Product	Period
Canigen L4 (EMEA/V/C/004079)	03.07.2015-31.01.2016
Emdocam (EMEA/V/C/002283)	01.03.2015-29.02.2016
Equisolon (EMEA/V/C/002382)	13.09.2015-12.03.2016
ERYSENG (EMEA/V/C/002761)	01.08.2015-31.01.2016
ERYSENG PARVO (EMEA/V/C/002762)	01.08.2015-31.01.2016
Innovax ILT (EMEA/V/C/003869)	03.07.2015-31.01.2016
Locatim (EMEA/V/C/000041)	01.01.2013-31.12.2015
Melosus (EMEA/V/C/002001)	01.03.2015-29.02.2016
NEXGARD SPECTRA (EMEA/V/C/003842)	01.08.2015-31.01.2016
Nobilis Influenza H5N2 (EMEA/V/C/000118)	01.03.2015-29.02.2016
Nobivac L4 (EMEA/V/C/002010)	03.07.2015-31.01.2016
Nobivac Myxo RHD (EMEA/V/C/002004)	01.04.2015-31.03.2016
RevitaCam (EMEA/V/C/002379)	01.09.2015-29.02.2016
Versican Plus DHPPi (EMEA/V/C/003679)	01.08.2015-31.01.2016

Versican Plus L4 (EMEA/V/C/003680)	01.08.2015-31.01.2016
Versican Plus Pi/L4 (EMEA/V/C/003683)	01.08.2015-31.01.2016
ZACTRAN (EMEA/V/C/000129)	01.02.2013-31.01.2016
ZULVAC 1 Bovis (EMEA/V/C/002334)	01.03.2015-29.02.2016
ZULVAC SBV (EMEA/V/C/002781)	01.09.2015-29.02.2016

- 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.

6. CO-OPERATION WITH OTHER EU OR INTERNATIONAL BODIES

6.1 VICH

- The Committee endorsed the draft EU comments on the concept paper on the need to elaborate on the next steps in the global approach to demonstrate bioequivalence.
- The Committee endorsed the draft EU comments on the draft concept paper for a general combination products guideline.
- The Committee endorsed the draft EU comments on the proposed draft annex for climatic zones III and IV to the VICH GL3(R) on stability: stability testing of new veterinary drug substances and medicinal products.
- The Committee endorsed the draft VICH guideline on studies to evaluate the metabolism and residue kinetics of veterinary drugs in food-producing species: study design recommendations for residue studies in honey for establishing MRLs and withdrawal periods, to be forwarded to the expert working group for sign off at step 2 of the VICH procedure.
- The Committee discussed the draft VICH guideline on studies to evaluate the metabolism and residue kinetics of veterinary drugs in food-producing species: marker residue depletion studies to establish product withdrawal periods in aquatic species.
- The Committee was informed of the meeting documents for the 33rd VICH Steering Committee meeting to be held on 20-23 June 2016 in Brussels, including the draft agenda, the draft minutes of the 32nd VICH Steering Committee, an update on the VICH GLs which have passed the 5 years of implementation, the progress report from the Electronic standards implementation Expert Working Group, the progress report from the VICH Quality Expert Working Group, the progress report from the VICH Biologicals Quality Monitoring Expert Working Group, the progress report from VICH Metabolism and Residue Kinetics Expert Working Group, the progress report from VICH Safety Expert Working Group products, the progress report from the VICH Anthelmintics Expert Working Group and the progress report from the VICH Combination products Task Force.

6.2 Codex Alimentarius

- There were no items for discussion.

6.3 Other EU bodies and international organisations

Information relating to certain topics discussed under section 6.3 cannot be released at the present time as it is deemed to be confidential.

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 re-elected unanimously Rory Breathnach as chair of the SAWP-V, for a further 3-year term.
- The Committee appointed Noemi Garcia del Blanco as member of the SAWP-V, for a 3-year term.
- The Committee received a verbal report from the chair of the SAWP-V on the meeting held on 14 June 2016, 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 31 May - 2 June 2016, and noted the agenda of the meeting.
- The Committee adopted the question and answer document on product specific active substance information, foreseen to be adopted by CHMP at their June meeting.
- The Committee agreed for the EWP-V and QWP to finalise the revision of the CVMP guideline on the conduct of efficacy studies for intramammary products for use in cattle, following the end of the 2nd round of public consultation – *see also 7.5*.
- The Committee discussed the reflection paper on definition of new active substance status – veterinary, which is foreseen to be adopted for release for public consultation at the July 2016 meeting.

7.3 Safety Working Party (SWP-V)

- The Committee received a verbal report from the chair of the SWP-V on the meeting held on 26-27 May 2016, and noted the agenda of the meeting.
- The Committee adopted the guideline on user safety of topically applied veterinary medicinal products (EMA/CVMP/SWP/721059/2014) for a 6-month period of public consultation.
- The Committee discussed the draft guideline on the approach towards harmonisation of withdrawal periods, which is foreseen to be adopted at the July 2016 CVMP meeting.
- The Committee agreed the draft programme for a proposed training event on genotoxicity testing.
- The Committee was informed of the updated draft guideline on DNA reactive impurities in veterinary medicinal products.

7.4 Environmental Risk Assessment Working Party (ERAWP)

- The Committee discussed the problem statement on the proposed reflection paper on antimicrobial resistance due to presence of veterinary antimicrobials in the environment. The problem statement will be presented for adoption at the July CVMP meeting.
- The Committee discussed the guideline on the higher tier testing of veterinary medicinal products to dung fauna, which is foreseen to be adopted at the July 2016 CVMP meeting.
- The Committee was informed of the final programme for the workshop on the environmental risk assessment for veterinary medicinal products for use on aquaculture, to be held on 22-23 June 2016.

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 31 May – 1 June 2016, and noted the agenda of the meeting as well as the draft minutes of the meeting held on 23-24 February 2016.
- The Committee endorsed that EWP-V and QWP finalise the revision of the CVMP guideline on the conduct of efficacy studies for intramammary products for use in cattle, following the end of the 2nd round of public consultation – *see also 7.2*.
- The Committee deferred the discussion on the draft concept paper for the revision of the guideline on anticoccidials for the therapy of coccidiosis in chickens, turkeys and geese (7AE15a Vol. 7) to the July 2016 CVMP meeting.
- The Committee deferred the discussion on the scope of the draft concept paper for the revision of the guideline for veterinary medicinal products for zootechnical purposes (NtA 7AE7a Vol. 7) for the July 2016 CVMP meeting.
- The Committee deferred the discussion on the revised guideline on the testing and evaluation of the efficacy of antiparasitic substances for the treatment and prevention of tick and flea infestations in dogs and cats and the overview of comments received for the July 2016 CVMP meeting.
- The Committee deferred the verbal update and discussion of the EWP-V Interested Parties meeting held on 1 June 2016 to the July 2016 CVMP meeting.
- The Committee deferred the verbal update and discussion on the Focus Group Meeting on the revision of the reflection paper on anthelmintic resistance held on 13 June 2016 to the July 2016 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 25-26 May 2016 of the meeting to the July 2016 CVMP meeting.
- The Committee discussed the first draft of the concept paper on the revision of the current guideline on the SPC for the antimicrobial products, which is foreseen to be adopted for release for public consultation at the July 2016 CVMP meeting.

7.7 Immunologicals Working Party (IWP)

- The Committee deferred the endorsement of the proposal for a training event on efficacy of immunological veterinary medicinal products to the July 2016 CVMP meeting.

7.8 Pharmacovigilance Working Party (PhVWP-V)

- The Committee deferred the verbal report from the chair of the PhVWP-V on the meeting held on 24-25 May 2016 to the July 2016 CVMP meeting.
- The Committee adopted the CVMP combined VeDDRA list of clinical terms for reporting suspected adverse reactions in animals and humans to veterinary medicinal products (EMA/CVMP/PhVWP/10418/2009 - Rev.8) and the list of changes (EMA/CVMP/PhVWP/286361/2016).
- The Committee adopted the guidance notes on the use of VeDDRA terminology for reporting suspected adverse reactions in animals and humans (EMA/CVMP/PhVWP/288284/2007 - Rev9).
- The Committee discussed the question and answer document on expressing the frequency of adverse reactions within the product information, which is foreseen to be endorsed by CVMP at the July 2016 meeting.
- The Committee deferred the verbal report on the surveillance workshop held on 25 May 2016 to the July 2016 CVMP meeting.
- The Committee was informed of the updated call for comments on the VeDDRA standard list for EVVet.

7.9 Novel therapy groups and related issues

- The Committee adopted the problem statement on stem cell-based products for veterinary use: specific questions on extraneous agents to be addressed by ADVENT (EMA/CVMP/ADVENT/174610/2016) for a 3-month period of public consultation.
- The Committee was informed of the end of the public consultation on problem statements on stem cell-based products for veterinary use: specific questions on sterility, and the overview of comments received, and on monoclonal antibodies for veterinary use: specific questions, and the overview of comments received.

7.10 Joint CVMP/CHMP AHEG on the application of the 3Rs (JEG-3Rs)

- There were no items for discussion.

7.11 Other working party and scientific group issues

- There were no items for discussion.

The following documents were circulated for information:

- Minutes of the SAWP-V meeting held on 17 May 2016;
- Agenda of the Joint CHMP/CVMP QWP Interested Parties meeting held on 1 June 2016;
- Agenda of the EWP-V Interested Parties meeting held on 1 June 2016 and list of participants;
- Draft agenda of the Focus Group Meeting on the revision of the reflection paper on anthelmintic resistance held on 13 June 2016;
- Draft minutes of the IWP meeting held on 11–12 February 2016;
- Draft agenda of the IWP meeting held on 29–30 June 2016;
- Draft minutes of the ADVENT meeting held on 19 May 2016;
- Draft agenda of the ADVENT meeting held on 15 June 2016;

- Registration to the conference organised by the European Commission on 'Non-Animal Approaches - The Way Forward' to be held on 6–7 December 2016 in Brussels. The conference is to engage the scientific community and relevant stakeholders in a debate on how to exploit cutting edge advances in biomedical and other research in the development of scientifically valid non-animal approaches (alternatives to animal testing). (http://www.euconf.eu/non-animal-approaches-the-way-forward/en/registration/index.html).

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.

- There were no items for discussion.

8.2 Environmental risk assessment

- The Committee noted the comments received during the public consultation on the reflection paper on the authorisation of veterinary medicinal products containing PBT/vPvB substances (EMA/CVMP/448211/2015), and agreed that the PBT AHEG should be reconvened for the revision of the reflection paper.

8.3 Antimicrobial resistance

- The Committee deferred the verbal report on the Veterinary Committee on Antimicrobial Susceptibility Testing (VetCAST) teleconference held on 23 May 2016 for the July 2016 CVMP meeting.
- The Committee deferred the item on the publication for consultation of the updated opinion of the Expert Advisory Group on Antibiotic Resistance (AMEG) on the use of colistin products in animals within the European Union (EMA/231573/2016) to the July 2016 CVMP meeting to allow an extension to the period of public consultation.
- The Committee deferred the verbal report on the 2nd Joint Inter-agency Antimicrobial Consumption and Resistance Analysis (JIACRA) to the July 2016 CVMP meeting.

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 deferred the verbal report on the simulation exercise for the incident management plan for medicines for veterinary use to the July 2016 CVMP meeting.

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.

- The Committee agreed to the transfer of all (co-)rapporteurship and peer reviewer responsibilities from M. Tollis to P. Pasquali and to transfer the co-rapporteurship for Incurin from V. Donini to P. Pasquali.

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.

- The Committee deferred the verbal update on the Notice to Applicants meeting held on 7 June 2016 for the July 2016 CVMP meeting.

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

- The Committee noted the draft minutes of the meeting held on 19-20 May 2016 as well as the draft agenda of the meeting held on 16-17 June 2016.

12. ORGANISATIONAL AND STRATEGIC MATTERS

- The Committee elected unanimously David Murphy as chair of the CVMP, for a 3-year term.
- The Committee endorsed the agenda of the CVMP/CMDv Presidency meeting to be held on 27-28 June 2016 in the Netherlands.
- The Committee was informed of the revision of the procedure for nomination and appointment of co-opted members in CHMP, CVMP and HMPC. A formal agreement is foreseen at the July 2016 CVMP meeting.
- The Committee deferred the discussion on the revised VNeeS format requirements guideline in force from 1 July 2016 (EMA/457952/2014) and the revision of the document on exceptions to VNeeS format (EMA/277096/2015) to the July 2016 CVMP meeting.
- The Committee deferred the item on the Council Decision of 29 May 2016 on the appointment of four Management Board members, including a veterinary representative to the July 2016 CVMP meeting.
- The Committee deferred the intended revision of the dossier submission requirements document to the July 2016 CVMP meeting.

13. LEGISLATION

- The Committee deferred the update on the development of CVMP recommendations for methodological principles for the risk assessment and risk management recommendations for the July 2016 CVMP meeting.

14. ANY OTHER BUSINESS

- Upon the completion of the June 2016 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 June 2016 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**	
AT	Barbara Zemann	Cannot act as rapporteur or peer reviewer for:	• 2.1 Metacam (EMEA/V/C/000033/X/0129)
BE	Bruno Urbain	Full involvement	
CY	Alia Michaelidou-Patsia	Full involvement	
CZ	Jiří Bureš	Full involvement	
DE	Cornelia Ibrahim	Full involvement	
DK	Ellen-Margrethe Vestergaard	Full involvement	
EE	Toomas Tiirats	Full involvement	
ES	Cristina Muñoz Madero	Full involvement	
FR	Jean-Claude Rouby	Full involvement	
HR	Ljiljana Markuš-Cizelj	Full involvement	
HU	Gábor Kulcsár	Full involvement	
IT	Paolo Pasquali	Full involvement	
LU	Marc Schmit	Full involvement	
LV	Zanda Auce	Full involvement	
PT	João Pedro Duarte da Silva	Full involvement	
SE	Eva Lander Persson	Full involvement	
SI	Stane Srčič	Cannot act as rapporteur or peer reviewer for:	• 4.3 Gentamicin (EMEA/V/A/117)
UK	Helen Jukes	Full involvement	
Co-opted	Keith Baptiste	Full involvement	
Co-opted	Rory Breathnach	Full involvement	
Co-opted	Christian Friis	Full involvement	
Co-opted	Wilhelm Schlumbohm	Full involvement	
Co-opted	Jason Weeks	Full involvement	
IS	Jóhann Lenharðsson	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
BE	Frédéric Klein	Full involvement	
DE	Esther Werner	Full involvement	
EL	Angeliki Tsigouri	Full involvement	
ES	Consuelo Rubio Montejano	Cannot act as rapporteur or peer reviewer for:	• 3.3 Bravecto (EMEA/V/C/002526/II/0011) • 3.3 Activyl Tick Plus

Country	CVMP Alternate	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
			(EMEA/V/C/002234/II/0008) • 5.4 Panacur AquaSol (EMEA/V/C/002008/R/0011) • 5.5 PSURs for Innovax ILT, Nobivac Myxo-RHD, Nobilis Influenza H5N2, Nobivac L4 & Canigen L4 • 10.2 one item
FR	Sylvie Louet	Full involvement	
IE	J. Gabriel Beechinor	Full involvement	
NL	Peter Hekman	Full involvement	
PL	Ewa Augustynowicz	Full involvement	
RO	Simona Sturzu	Full involvement	
SE	Frida Hasslung Wikström	Full involvement	
SK	Eva Chobotová	Full involvement	
UK	Noemi Garcia del Blanco	Full involvement	
NO	Tonje Høy (remote)	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.			
DE	Ina Ebert *(remotely)*	Full involvement	
DE	Sabine Klee	Full involvement	
DE	Wolfgang Koch *(remotely)*	Full involvement	
DE	Susanne Schmitz	Full involvement	
DK	Anne Engelbrecht Thomsen *(remotely)*	Full involvement	
DK	Lotte Gam Pedersen	Full involvement	
DK	John Jensen *(remotely)*	Full involvement	
DK	Niels Christian Kyvsgaard *(remotely)*	Full involvement	
DK	Lisbet Vesterager Borge *(remotely)*	Full involvement	
ES	Ricardo Carapeto García	Full involvement	
ES	Mercedes Conradi Moner *(remotely)*	Full involvement	
ES	Aránzazu González Canga *(remotely)*	Full involvement	
ES	María Amparo Haro Castuera *(remotely)*	Full involvement	
IE	Susan Reid	Full involvement	
NL	Jacqueline Poot *(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
NL	Johan Schefferlie *(remotely)*	Full involvement	
NL	Sandra ten Voorde *(remotely)*	Full involvement	
NO	Tonje Hoy *(remotely)*	Full involvement	
SE	Åsa Bertilsson *(remotely)*	Full involvement	
UK	Sam Fletcher *(remotely)*	Full involvement	
UK	Mike Stephens *(remotely)*	Full involvement	

CVMP working parties and CMDv	Chair
ADVENT	Jean-Claude Rouby
AWP	Helen Jukes
CMDv	Gavin Hall
ERAWP	Jason Weeks
EWP-V	Gesine Hahn
IWP	Esther Werner
PhVWP-V	Peter Ekström *(remotely)*
QWP	Mary O'Grady *(Vet vice chair - remotely)*
SAWP-V	Rory Breathnach
SWP-V	Eva Lander Persson

Observer from the European Commission	
Present	

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