13 January 2015
EMA/CVMP/25865/2015
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Minutes of the 9-11 December 2014 meeting

Chair: A. Holm – Vice-chair: D. Murphy

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 the addition of a new item for information, on the Article 78 referral on HIPRABOVIS PNEUMOS, under point 4.7.

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

The attendance list was completed and conflicts of interests were identified for the December 2014 meeting. In accordance with the Agency's revised policy and procedure on the handling of conflicts of interests, participants in this meeting were asked to declare any conflict of 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.

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

Information relating to certain 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.

A number of CVMP members received during the meeting an email with regard to the Article 30(3) procedure on diclofenac. The email was not taken into account in the discussion of the procedure.

iv. Adoption of the minutes of the previous meeting

The minutes of the November 2014 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 was informed that the CVMP opinion including the EPMAR and the CVMP assessment report recommending the maintenance of the existing MRLs for **potassium selenite, sodium selenate and sodium selenite** (EMEA/V/MRL/003225/MODF/0002) had been adopted via written procedure on 4 December 2014 by consensus (28 members voting of those eligible to vote). The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP. The Committee noted the summary opinion for publication.

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 discussed the response to the list of questions for the review of the previous opinion for the establishment of MRLs for **diflubenzuron** (EMEA/V/MRL/003135/MODF/0003) in Salmonidae. The review follows a request from the European Commission under Article 11 of Regulation (EC) No. 470/2009.

2. COMMUNITY MARKETING AUTHORISATIONS AND EXTENSIONS

2.1 Opinions

- The Committee adopted by consensus (30 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **Suvaxyn CSF**

Marker (EMEA/V/C/002757/0000), recommending the granting of a marketing authorisation. The product is a new viral vaccine containing live recombinant bovine viral diarrhoea virus, containing the classical swine fever E2 marker (CP7-E2alf), with DIVA possibilities. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP. The Committee noted the summary of opinion for publication.

- The Committee adopted by consensus (30 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **Zulvac SBV** (EMEA/V/C/002781/0000), recommending the granting of a marketing authorisation. The product is a new viral vaccine against Schmallenberg virus in sheep and cattle. The Icelandic and Norwegian CVMP members 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 heard an oral explanation from the applicant concerning an application for a new cardiovascular product for cats (EMEA/V/C/003786/0000). The Committee also discussed the draft product information and the rapporteurs' assessment of the responses to the list of outstanding issues. An opinion is foreseen for the January 2015 CVMP meeting.
- The Committee adopted the updated scientific overview and benefit-risk assessment including the list of outstanding issues for a grouped extension application for **Stronghold** (EMEA/V/C/000050/X/0051/G), to include new strengths for cats and dogs. The Committee agreed that an oral explanation would not be necessary. The Committee discussed the draft product information. An opinion is foreseen for the January 2015 CVMP meeting.
- The Committee adopted the updated scientific overview and benefit-risk assessment including the list of outstanding issues for an extension application for **Rheumocam** (EMEA/V/C/000121/X/0015), to include a new strength for horses. The Committee agreed that an oral explanation would not be necessary. The Committee discussed the draft product information and noted a peer review report and the comments received from CVMP members.
- The Committee adopted the updated scientific overview and benefit-risk assessment including the list of outstanding issues for a marketing authorisation application for a new cardiovascular product for dogs (EMEA/V/C/002804/0000). The Committee discussed the draft product information and noted three peer review reports and the comments received from CVMP members.
- The Committee adopted the updated scientific overview and benefit-risk assessment including the list of outstanding issues for a marketing authorisation application for a new product (EMEA/V/C/003797/0000), a live bacterial vaccine for pigs. The Committee discussed the draft product information and noted a peer review report and the comments received from CVMP members. An opinion is foreseen for the January 2015 CVMP meeting.

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 an extension application for **DRAXXIN** (EMEA/V/C/000077/X/0029), to add a new target species. The Committee noted two peer review reports, the comments from AWP 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 product

(EMEA/V/C/003942/0000), a viral vaccine for pigs. The Committee noted two peer review reports 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 was informed of the formal notification from New A Innovation (NL) Limited B.V. of their decision to withdraw the application for a new marketing authorisation procedure for **Oxapex** (EMEA/V/C/002794/0000), a new haematological product for dogs. More information about this application and the current state of the scientific assessment at the time of the withdrawal will be made available in a public assessment report.

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

- The Committee adopted by consensus (28 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for a grouped quality type II variation for **Easotic** (EMEA/V/C/000140/II/0006/G), recommending the variation of the marketing authorisation. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP.

- The Committee adopted by consensus (30 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for a grouped quality type II variation for **Equip WNV** (EMEA/V/C/000137/II/0018/G), recommending the variation of the marketing authorisation. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP.

- The Committee adopted by consensus (30 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for a worksharing type II variation for **LEUCOFELIGEN FeLV/RCP and LEUCOGEN** (EMEA/V/C/xxxxxx/WS/0639), recommending the variation of the marketing authorisations to update the product information in relation to ranking of adverse reactions. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP.

3.2 Oral explanations and lists of outstanding issues

- The Committee adopted the list of outstanding issues to be addressed in writing for a type II variation for **Broadline** (EMEA/V/C/002700/II/0001), to add new indications.

- The Committee heard an oral explanation from MSD Animal Health concerning a grouped type II variation for **Zuprevo** (EMEA/V/C/002009/II/0006/G), to add a new indication and to delete a precautionary statement. The Committee also discussed the rapporteurs' assessment of the responses to the list of outstanding issues.

- The Committee adopted the list of outstanding issues to be addressed in writing for a worksharing type II variation for **Purevax RCPCh, Purevax RCP, Purevax RC, Purevax RCPCh FeLV and Purevax RCP FeLV** (EMEA/V/C/xxxxxx/WS/0606), to extend the duration of immunity after revaccination. The adoption of the opinion was postponed until the January 2015 CVMP meeting.

3.3 Lists of questions

- The Committee adopted the list of questions for a type II variation for **Poulvac E. coli** (EMEA/V/C/002007/II/0006/G), to include an additional route of administration. The product is classified as MUMS.
- The Committee adopted the list of questions for a worksharing type II variation for **Nobilis IB 4-91** (EMEA/V/C/000036/WS/0607(0006)), to add a claim for the mixed-use of Nobilis IB 4-91 and Nobilis IB Ma5.

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

- There were no items for discussion.

4.3 Article 35 of Directive 2001/82/EC

- The Committee adopted by consensus (30 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for the referral procedure for **all veterinary medicinal products containing colistin to be administered orally** (EMEA/V/A/106), recommending a harmonised indication, a limitation of the duration of treatment up to 7 days and warning sentences on prudent use. The marketing authorisations of the concerned products should be varied in order to amend the product information accordingly. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP.

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

- The Committee discussed the European Commission's response to the CVMP's request for advice for the procedure in relation to **the potential risk for the consumer resulting from the use of lidocaine in food-producing species** (EMEA/V/A/092).
- The Committee adopted by consensus (23 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for the procedure concerning **the risk to vultures and other necrophagous bird populations in the European Union in connection with the use of veterinary medicinal products containing the substance diclofenac** (EMEA/V/A/107). The Committee identified scenarios in which vultures and other

bird species that consume carcasses (necrophagous birds) may be exposed to residues of diclofenac in the EU and, for each scenario, proposed a range of measures that could be put in place to minimise or eliminate the risk identified. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP.

4.7 Other issues

- The Committee was informed of the lifting of the suspension for **HIPRABOVIS PNEUMOS**, a product which had previously been the subject of an Article 78 referral procedure.

- ***The following documents were circulated for information:***
  - Resflor solution injectable and associated names - Article 13 referral (EMEA/V/A/101) – Background information for publication;
  - Suanovil 20 and associated names, Captalin and associated names and generic products thereof - Article 35 referral (EMEA/V/A/086) – Background information for publication.

5. POST-AUTHOIRSATION 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 adopted the rapporteur's assessment report on the data submitted concerning a condition for **Bovela** (EMEA/V/C/003703/ANX001); as the condition has now been fulfilled, Annex II of the Commission Decision will be amended at the next opportunity (e.g. a variation amending the product information).
- The Committee adopted the rapporteur's assessment report on the data submitted concerning a recommendation for **Cortavance** (EMEA/V/C/000110/REC017).
- The Committee adopted the rapporteur's assessment report on the data submitted concerning a recommendation for **Equilis Te** (EMEA/V/C/000093/REC012).
- The Committee adopted the rapporteur's assessment report on the data submitted concerning a recommendation for **Porcilis AR-T DF** (EMEA/V/C/000055/REC022).

5.3 Product anniversary list

- The Committee endorsed the product anniversary list for the period between 07.11.2014 – 11.12.2014:

Product	Period
Acticam (EMEA/V/C/000138)	09.12.2013 – 08.12.2014
Broadline (EMEA/V/C/002700)	04.12.2013 – 03.12.2014
Contacera (EMEA/V/C/002612)	06.12.2013 – 05.12.2014
DRAXXIN (EMEA/V/C/000077)	11.11.2013 – 10.11.2014
Easotic (EMEA/V/C/000140)	20.11.2013 – 19.11.2014

Product	Period
Equip WNV (EMEA/V/C/000137)	21.11.2013 – 20.11.2014
Inflacam (EMEA/V/C/002497)	09.12.2013 – 08.12.2014
Masivet (EMEA/V/C/000128)	17.11.2013 – 16.11.2014
Meloxivet (EMEA/V/C/000124)	14.11.2013 – 13.11.2014
Meloxoral (EMEA/V/C/000151)	19.11.2013 – 18.11.2014
Oxyglobin (EMEA/V/C/000045)	29.11.2013 – 28.11.2014
Panacur AquaSol (EMEA/V/C/002008)	09.12.2013 – 08.12.2014
Porcilis AR-T DF (EMEA/V/C/000055)	16.11.2013 – 15.11.2014
Quadrisol (EMEA/V/C/000032)	04.12.2013 – 03.12.2014
SevoFlo (EMEA/V/C/000072)	11.12.2013 – 10.12.2014
Stronghold (EMEA/V/C/000050)	25.11.2013 – 24.11.2014
Vectra 3D (EMEA/V/C/002555)	04.12.2013 – 03.12.2014

5.4 Renewals

- There were no items for discussion.

5.5 Pharmacovigilance – PSURs and SARs

- The Committee discussed the request from the MAH for the re-consideration of the CVMP outcome of the 2nd PSUR assessment for **Pexion** (EMEA/V/C/002543), and exceptionally agreed to delay the decision until January 2015.
- The Committee agreed a revised timetable for PSUR assessments foreseen for completion at the February 2015 CVMP meeting.
- The Committee adopted the following CVMP PSUR assessment reports concluding that no changes to the product literature or other regulatory actions were required at this stage for:

Product	Period
Activyl Tick Plus (EMEA/V/C/002234)	01.02.2014 – 31.07.2014
BROADLINE (EMEA/V/C/002700)	04.12.2013 – 30.06.2014
CORTAVANCE (EMEA/V/C/000162)	01.08.2011 – 31.07.2014
ECOPORC SHIGA (EMEA/V/C/002535)	01.02.2014 – 31.07.2014
Gripovac 3 (EMEA/V/C/000157)	01.08.2013 – 31.07.2014
Nobivac L4 (EMEA/V/C/002010)	01.02.2014 – 31.07.2014
PIRSUE (EMEA/V/C/000054)	01.08.2011 – 31.07.2014
Reconcile (EMEA/V/C/000133)	01.08.2013 – 31.07.2014
RESPIPORC FLU3 (EMEA/V/C/000153)	01.08.2013 – 31.07.2014

Rheumocam (EMEA/V/C/000121)	01.02.2014 – 31.07.2014
Semintra (EMEA/V/C/002436)	01.03.2014 – 31.08.2014
ZULVAC 8 Bovis (EMEA/V/C/000145)	01.02.2014 – 31.07.2014
ZULVAC 8 Ovis (EMEA/V/C/000147)	01.02.2014 – 31.07.2014

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

5.6 Supervisions and sanctions

Information relating to supervisions 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 endorsed the draft EU comments on the summary of point 3 of the discussion paper concerning topics 1-3 and on the draft discussion paper concerning topic 4 of the VICH Task Force on the revision of anthelmintic guidelines.
- The Committee discussed the draft EU comments on the revised draft VICH GL48 on marker residue depletion studies to establish product withdrawal periods in aquatic species. It was agreed that the draft comments would be updated and brought back to the January meeting for adoption.
- The Committee endorsed the revised draft guideline on study design recommendations for residue depletion studies in honey for establishing MRLs and withdrawal periods, to be circulated to the VICH expert working group.
- The Committee adopted the draft EU comments on the revised draft concept paper from the Task Force leader of the VICH Expert Working Group on Quality - Task Force on revision of (Stability) GL3 (R) subject to some minor editorial amendments agreed by the CVMP.
- The Committee received an update on the VICH GL 52 on bioequivalence: blood level bioequivalence study, which is near completion for sign off at step 6 of the procedure.

6.2 Codex Alimentarius

- The Committee discussed the draft Codex MRLs and the use of the Estimated Daily Intake (EDI) as well as revised draft CVMP comments on the draft Codex MRLs for consideration at the 22nd CCRVDF meeting. Some concerns were identified and it was agreed that a revised version would be circulated to CVMP members for written comments.
- The Committee supported the draft EU comments relating to provisions on the establishment of MRLs for honey, and noted the report from the 21st CCRVDF meeting.

6.3 Other EU bodies and international organisations

- The Committee received an update on the Joint EMA/HMA workshop on requirements for the authorisation of vaccines in the EU, which is scheduled to take place on 25 March 2015 in London, UK.

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 9 December 2014, and noted the agenda of the meeting.

7.2 Quality Working Party (QWP)

- There were no items for discussion.

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 27-28 November 2014, and noted the agenda of the meeting.
- The Committee discussed the draft guideline on genotoxic impurities and the comments received from QWP and EWP-V. SWP-V will update the document in light of the comments received and the discussions that have taken place.
- The Committee deferred the discussion on the note for guidance on the approach towards harmonisation of withdrawal periods – comparing approaches for dealing with results below the limit of quanitification.
- The Committee adopted the veterinary parts of the overview of comments received on the draft guideline on setting health based exposure limits for use in risk identification in the manufacture of different medicinal products in shared facilities.
- The Committee discussed the draft guideline on risk characterisation and assessment of MRLs for biocides used in animal husbandry and the overview of comments received. The guideline is foreseen to be adopted at the January 2015 meeting of the Committee.

7.4 Environmental Risk Assessment Working Party (ERAWP)

- The Committee postponed the verbal report from the chair of the ERAWP on the meeting held on 21-22 October 2014 until the January 2015 meeting, but noted the minutes of the meeting.

7.5 Efficacy Working Party (EWP-V)

- The Committee postponed the verbal report from the chair of the EWP-V on the meeting held on 25-26 November 2014 until the January 2015 meeting, but noted the agenda of the meeting.

- The Committee deferred the discussion on the revised guideline for the demonstration of efficacy for veterinary medicinal products containing antimicrobial substances until the January 2015 meeting.

7.6 Antimicrobials Working Party (AWP)

- The Committee postponed the verbal report from the chair of the AWP on the meeting held on 18-19 November 2014 until the January 2015 meeting, but noted the agenda of the meeting.

7.7 Immunologicals Working Party (IWP)

- The Committee adopted the reflection paper on the replacement of cell lines used for the production of immunological veterinary medicinal products (IVMPs) (EMA/CVMP/IWP/37620/2014) for a 3-month period of public consultation.
- The Committee adopted the reflection paper on the use of heat treatment to inactivate retrovirus RD114 in live immunological veterinary medicinal products (IVMPs) (EMA/CVMP/IWP/37924/2014) for a 3-month period of public consultation.

7.8 Pharmacovigilance Working Party (PhVWP-V)

- The Committee received a verbal report from the chair of the PhVWP-V on the meeting held on 18-19 November 2014, and noted the draft minutes of the meeting.
- The Committee noted the draft agenda of the Focus Group meeting on pharmacovigilance surveillance/signal detection.

7.9 Novel therapy groups and related issues

- The Committee adopted the mandate and rules of procedure (EMA/CVMP/ADVENT/630299/2014) for the Ad Hoc Group on Novel Veterinary Therapies (ADVENT).
- The Committee appointed the following as members of ADVENT: W. Schlumbohm, D. Murphy, C. Muñoz Madero, J.-C. Rouby, E. Werner, D. Śladowski.
- The Committee discussed the ADVENT work plan 2015 which was proposed for adoption in January 2015.
- The Committee noted the call for expressions of interest for the chair of the ADVENT core group. The election for a two-year mandate period would take place at the January 2015 meeting of the CVMP.

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

- The Committee received a verbal report from the chair of the JEG-3Rs on the meeting held on 27-28 October 2014, and noted the agenda of the meeting.
- The Committee discussed the combined comments received during the public consultation of the concept paper on transferring quality control methods validated in collaborative trials to a product/laboratory specific context and indicated its support for development of the proposed guidance.
- The Committee further discussed aspects of the JEG 3Rs draft work plan for 2015-2016. No revisions to the work plan, adopted by CVMP at its November 2014 meeting, were made.

7.11 Other working party and scientific group issues

The following documents were circulated for information:

- Minutes of the SAWP meeting held on 4 November 2014;
- Draft agenda for the 73rd Joint CHMP/CVMP QWP meeting held on 3-5 December and final minutes of the 72nd Joint CHMP/CVMP QWP meeting held on 17-19 September;
- Summary Record of the Joint meeting of the GMP/GDP Inspectors Working Group and CHMP/CVMP Quality Working Party meeting held on 17 September 2014;
- Minutes of the 59th EWP meeting held on 30 September – 1 October 2014;
- Draft minutes of the IWP meeting held on 30 September – 1 October 2014.

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.

- The Committee agreed to include **phosphodiester oligodeoxynucleotides** as a new entry in the list of substances considered as not falling within the scope of Regulation (EC) No 470/2009 for use as adjuvants, following the request from the applicant.
- The Committee adopted the revised list of substances considered as not falling within the scope of Regulation (EC) No 470/2009 (EMA/CVMP/519714/2009 – Rev.24).

8.2 Environmental risk assessment

- There were no items for discussion.

8.3 Antimicrobial resistance

- The Committee adopted the final answers to question 2 (ranking of antibiotics), question 3 (new antibiotics) and question 4 (risk mitigation options) in relation to the request for scientific advice on the impact on public health and animal health of the use of antibiotics in animals. The overview of comments after the second consultation was also adopted. The answers would be sent to the CHMP for adoption.

  A workshop on the answers provided is planned by the European Commission to take place during 2015.

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.

- There were no items for discussion.

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.

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

- The Committee received a verbal report from the chair of CMDv of the meeting held on 6-7 November 2014 and noted the draft agenda of the meeting to be held on 11-12 December 2014.

12. ORGANISATIONAL AND STRATEGIC MATTERS

- The Committee discussed the revised document on the appointment and responsibilities of the rapporteur and co-rapporteur for procedures regarding veterinary medicinal products and noted the table to declare potential interest in participating in a multinational assessment team and the expertise available per National Competent Authority.
- The discussion on the guidance on the principles to prepare CVMP assessment reports, and the templates for scientific overview and benefit-risk assessment and list of questions (pharmaceutical) was deferred until the January 2015 meeting.
- The CVMP noted the draft programme for the 2015 EMA/IFAH-Europe Info Day, to be held in London on 12-13 March 2015 which had been discussed by the Strategic Planning Group. Members were invited to send any comments or proposals to the secretariat.
- The Committee endorsed the draft minutes of the Presidency CVMP meeting and joint CVMP/CMDv meeting, held on 22-23 September 2014 in Rome, Italy.
- The Committee received a verbal report from the chair of the Strategic Planning Group on the meeting held on 10 December 2014, and noted the agenda of the meeting and the minutes of the meeting held on 10 September 2014.
- The Committee noted the table of actions following the November 2014 CVMP meeting.

13. LEGISLATION

- There were no items for discussion.

14. ANY OTHER BUSINESS

- Upon the completion of the December 2014 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 December 2014 meeting

Country	CVMP Member	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
CHAIR	**Anja Holm**	**Full involvement**	
AT	Barbara Zemann	Cannot act as rapporteur or peer reviewer for:	• 3.1 - Equip WNV (EMEA/V/C/000137/II/0018/G) • 5.2 – Bovela (EMEA/V/C/003703/ANX001) • 5.5 – Semintra, Pexion • 10.1 – one item
BE	Bruno Urbain	Full involvement	
BG	Emil Kozhuharov	Full involvement	
CY	Alia Michaelidou	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	
FI	Irmeli Happonen	Full involvement	
HR	Ljiljana Markuš-Cizelj	Involvement in discussions only and cannot act as rapporteur for:	• 2.3 - EMEA/V/C/003942/0000 • 3.2 – Zuprevo (EMEA/V/C/002009/II/0006/G) • 3.3 - Nobilis IB 4-91 (EMEA/V/C/000036/WS/0607 (0006)) • 5.2 - Equilis Te (EMEA/V/C/000093/REC012) • 5.2 - Porcilis AR-T DF (EMEA/V/C/000055/REC022) • 5.5 - Activyl Tick Plus, Nobivac L4 • 5.6 – one item • 8.1 - Phosphodiester oligodeoxynucleotides
HU	Gábor Kulcsár	Full involvement	
IE	David Murphy (vice-chair)	Full involvement	
LV	Zanda Auce	Full involvement	
NL	Johan Schefferlie	Full involvement	
PL	Ewa Augustynowicz	Full involvement	
PT	João Pedro Duarte da Silva	Full involvement	
RO	Lollita Taban	Full involvement	
SE	Eva Lander Persson	Full involvement	

Country	CVMP Member	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
SI	Stane Srčič	Cannot act as rapporteur or peer reviewer for:	• 2.2 – EMEA/V/C/002804/0000 • 4.3 – Colistin (EMEA/V/A/106)
SK	Judita Hederová	Full involvement	
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	Boris Kolar	Cannot act as rapporteur or peer reviewer for:	• 4.3 – Colistin (EMEA/V/A/106)
Co-opted	Wilhelm Schlumbohm	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
DE	Esther Werner	Full involvement	
DK	Merete Blixenkrone-Møller	Full involvement	
EL	Angeliki Tsigouri	Full involvement	
ES	Consuelo Rubio Montejano	Full involvement	
FR	Jean-Claude Rouby	Full involvement	
IT	Virgilio Donini	Full involvement	
NL	Peter Hekman	Full involvement	
PL	Anna Wachnik-Święcicka	Full involvement	
SE	Frida Hasslung Wikström	Full involvement	
UK	Anna-Maria Brady	Full involvement	
NO	Tonje Høy	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	Stefan Scheid *(remotely)*	Full involvement	
DK	Henrik Friberg-Johansen *(remotely)*	Full involvement	
ES	Ricardo Carapeto Garcia	Full involvement	
FR	Hélène Amar-Deguerville	Full involvement	
FR	Nathalie Bridoux *(remotely)*	Full involvement	
IT	Maria Tollis *(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	Jacqueline Poot	No involvement with respect to:	• 1.5 - Diflubenzuron (EMEA/V/MRL/003135/MODF/0003) • 2.3 - Draxxin (EMEA/V/C/000077/X/0029)
SE	Fredrik Hulten *(remotely)*	Full involvement	
UK	Sharon Reynolds	Full involvement	

CVMP working parties and CMDv	Chair
AWP	Helen Jukes
CMDv	Gavin Hall
ERAWP	Boris Kolar
EWP-V	Gesine Hahn
IWP	Esther Werner
PhVWP-V	Peter Ekström (*remotely*)
QWP	Piet-Hein Overhaus *(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 secretariat.