4 November 2014
EMA/CVMP/682233/2014
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Minutes of the 7-9 October 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 no modifications.

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 October 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.

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.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5545
Send a question via our website www.ema.europa.eu/contact

iv. Adoption of the minutes of the previous meeting

The minutes of the September 2014 meeting were adopted with minor 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 consensus (29 members present of those eligible to vote) the CVMP opinion including the EPMAR and the CVMP assessment report recommending the modification of the MRL classification for **aluminium salicylate, basic** (EMEA/V/MRL/003298/MODF/0004) and the establishment of provisional maximum residue limits in bovine tissues and milk. The Committee also agreed to extrapolate these provisional maximum residue limits to caprine species, *Equidae* and rabbits. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP. The Committee noted the report from EU-RL, a peer review report and the comments received from CVMP members.

1.2 Oral explanations and lists of outstanding issues

- The Committee discussed the rapporteurs' joint assessment of the responses to the list of questions and the rapporteur's draft EPMAR for the establishment of MRLs in bovine species for a substance (EMEA/V/MRL/003915/FULL/0001) as well as the EU-RL comments concerning the analytical method, and adopted a list of outstanding issues that should be addressed in writing.

- The Committee discussed the rapporteurs' joint assessment of the responses to the list of questions and the rapporteur's draft EPMAR for the establishment of MRLs in chickens for a substance (EMEA/V/MRL/003878/FULL/0001) as well as the EU-RL comments concerning the analytical method, and agreed that an oral explanation would not be necessary. The adoption of the opinion is foreseen for the November 2014 meeting of the Committee.

1.3 Lists of questions

- The Committee discussed the rapporteur's assessment report including the critique from the co-rapporteur and two peer review reports for the establishment of MRLs in all food producing species for a substance (EMEA/V/MRL/004039/FULL/0001), as well as the comments from EFSA. The Committee agreed that a list of questions would not be necessary. The adoption of the opinion is foreseen for the November 2014 meeting of the Committee.

- The Committee discussed the rapporteur's assessment report including the critique from the co-rapporteur and the rapporteur's draft EPMAR for the modification of MRLs in bovine species for a substance (EMEA/V/MRL/003225/MODF/0002), and agreed to seek information on authorised products from member states. The evaluation will be discussed further at the November meeting with the adoption of the opinion foreseen in December 2014.

1.4 Re-examination of CVMP opinions

- The Committee discussed the request from the European Commission for reconsideration of the CVMP opinion for a substance, and agreed that a revised opinion and draft cover letter would be discussed at the November 2014 meeting of the Committee.

1.5 Other issues

- There were no items for discussion.

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 **Bovela** (EMEA/V/C/003703/0000), recommending the granting of a marketing authorisation. The product is a new viral vaccine containing modified live bovine viral diarrhoea virus type 1 and type 2 for the active immunisation of pregnant cattle against bovine viral diarrhoea virus. 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 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 cats (EMEA/V/C/003786/0000). The Committee discussed the draft product information 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 viral vaccine for pigs (EMEA/V/C/002757/0000). The Committee noted the draft product information and the rapporteurs' assessment of the responses to the list of outstanding issues, and exceptionally adopted a second list of outstanding issues to be addressed in writing.
- 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 antiparasitic product for dogs (EMEA/V/C/003842/0000). The Committee discussed the draft product information and noted a peer review report and the comments received from CVMP members.

2.3 Lists of questions

- There were no items for discussion.

2.4 Re-examination of CVMP opinions

- There were no items for discussion.

2.5 Other issues

- The Committee endorsed the withdrawal EPAR, following the formal notification from the applicant to withdraw their application for **Oncept Melanoma** (EMEA/V/C/003684/0000).
- The Committee endorsed the EPAR module 6 scientific discussion for **Nobilis IB Primo QX** (EMEA/V/C/002802/0000) concerning the granting of the initial marketing authorisation.

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

- The Committee adopted by consensus (30 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for a quality grouped type II variation for **ZACTRAN** (EMEA/V/C/00129/II/0026/G), recommending the variation of the marketing authorisation. 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 and at an oral explanation in December 2014 for a grouped type II variation for **Zuprevo** (EMEA/V/C/002009/II/0006/G) to add a new therapeutic indication and delete a precautionary statement.
- The Committee adopted the list of outstanding issues for a quality grouped type II variation for **Easotic** (EMEA/V/C/000140/II/0006/G).

3.3 Lists of questions

- The Committee adopted the list of questions for a quality worksharing type II variation for **ZULVAC 1 Bovis, ZULVAC 8 Bovis, ZULVAC 1+8 Bovis, ZULVAC 1 Ovis, ZULVAC 8 Ovis and ZULVAC 1+8 Ovis** (EMEA/V/C/xxxxxx/WS/0597).
- The Committee adopted the list of questions for a quality grouped type II variation for **Suvaxyn PCV** (EMEA/V/C/000149/II/0017/G).
- The Committee adopted the list of questions for a worksharing type II variation for **ERYSENG PARVO** (EMEA/V/C/002762/WS/0618) to update the product information.
- The Committee adopted the list of questions 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.
- The Committee adopted the list of questions for a worksharing type II variation for **LEUCOFELIGEN FeLV/RCP and LEUCOGEN** (EMEA/V/C/xxxxxx/WS/0639) to update the product information.

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

- The Committee considered the notification from the United Kingdom for a referral procedure for **Gutal 1000 g/kg premix for medicated feeding stuff for pigs** due to concerns expressed by France and the Netherlands regarding a potential risk to the environment from use of the product. The Committee agreed to start a referral procedure (EMEA/V/A/108) under

Article 33(4), and appointed P. Hekman as rapporteur and H. Jukes as co-rapporteur for the procedure. The Committee adopted a list of questions and a timetable for the procedure.

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 discussed the rapporteur's assessment report including the critique from the co-rapporteur following the responses to the list of outstanding issues for the referral procedure for **all veterinary medicinal products containing gentamicin presented as solutions for injection to be administered to horses** (EMEA/V/A/104). The Committee agreed that no further outstanding issues remained. The adoption of the CVMP opinion and assessment report is foreseen for the November 2014 meeting of the Committee. The Committee noted three peer review reports.

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

- The Committee adopted by majority (23 members in favour out of the 29 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for the referral procedure for **Resflor injectable solution for cattle** (EMEA/V/A/101), recommending the granting of the variation to the terms of the marketing authorisation relating to the addition of *Mycoplasma bovis* as a target organism for this veterinary medicinal product. The Icelandic CVMP member agreed with the above-mentioned recommendation of the CVMP. B. Zemann, H. Jukes, K. Baptiste, C. Ibrahim, J. Bureš, M. Blixenkrone-Møller and the Norwegian CVMP member signed a divergent position not supporting the aforementioned recommendation.

4.6 Article 30(3) of Regulation 726/2004

- The Committee discussed the joint rapporteurs' assessment report for the procedure **on risks 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 information received during the public consultation on the matter, finishing on 10 October 2014, would be incorporated in the revised joint rapporteurs' assessment report to be discussed at the November meeting. The CVMP agreed to invite stakeholders for an oral hearing during the November CVMP meeting, for which the questions would be finalised considering the information received from the public consultation and adopted by written procedure. The Committee adopted a revised timetable for the procedure, and noted a peer review report and the comments received.

4.7 Other issues

- There were no items for discussion.

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 12.09.2014 – 09.10.2014:

Product	Period
APOQUEL (EMEA/V/C/002688)	12.09.2013 – 11.09.2014
Cerenia (EMEA/V/C/000106)	29.09.2013 – 28.09.2014
COXEVAC (EMEA/V/C/000155)	30.09.2013 – 29.09.2014
Palladia (EMEA/V/C/000150)	23.09.2013 – 22.09.2014
Recocam (EMEA/V/C/002247)	13.09.2013 – 12.09.2014
Recuvyra (EMEA/V/C/002239)	06.10.2013 – 05.10.2014
RHINISENG (EMEA/V/C/000160)	16.09.2013 – 15.09.2014
Trifexis (EMEA/V/C/002635)	19.09.2013 – 18.09.2014

5.4 Renewals

- The Committee adopted by consensus (29 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for the renewal of **Gripovac 3** (EMEA/V/C/000157/R/0005). The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP. It was agreed that the authorisation should now be indefinite.

- The Committee adopted by consensus (30 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for the renewal of **RESPIPORC FLU3** (EMEA/V/C/000153/R/0006). The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP. It was agreed that the authorisation should now be indefinite.

5.5 Pharmacovigilance – PSURs and SARs

- The Committee adopted the CVMP assessment report of the PSUR for the period 01.10.2013 – 31.03.2014 for **Nobivac Myxo-RHD** (EMEA/V/C/002004) with a recommendation to amend section 4.2 of the SPC.

- The Committee adopted the CVMP assessment report of the PSUR for the period 01.09.2013 – 28.02.2014 for **Pexion** (EMEA/V/C/002543) with a recommendation to amend sections 4.4 and 4.6 of the SPC.

- The Committee adopted the CVMP assessment report of the PSUR for the period 20.06.2011 – 31.05.2014 for **ProMeris Duo** (EMEA/V/C/000108) with no proposed amendments.

- The Committee adopted the CVMP assessment report of the PSUR for the period 01.11.2013 – 30.04.2014 for **Recuvyra** (EMEA/V/C/002239) with a recommendation to amend sections 4.5 and 4.6 of the SPC.

- 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
Aivlosin (EMEA/V/C/000083)	01.10.2013 – 31.04.2014
APOQUEL (EMEA/V/C/002688)	01.12.2013 – 31.05.2014
BTVPUR AlSap 2-4 (EMEA/V/C/000139)	01.12.2013 – 31.05.2014
CERTIFECT (EMEA/V/C/002002)	01.12.2013 – 31.05.2014
EQUIOXX & Previcox (EMEA/V/C/000142)	01.07.2013 – 30.06.2014
LEUCOGEN (EMEA/V/C/000144)	01.07.2013 – 30.06.2014
MS-H Vaccine (EMEA/V/C/000161)	15.12.2013 – 14.06.2014
Oncept IL-2 (EMEA/V/C/002562)	01.12.2013 – 31.05.2014
ProMeris (EMEA/V/C/000107)	20.06.2011 – 31.05.2014
Vectra 3D (EMEA/V/C/002555)	04.12.2013 – 30.06.2014

- 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 (EMA/CVMP/497281/2006).

6. CO-OPERATION WITH OTHER EU OR INTERNATIONAL BODIES

6.1 VICH

- The Committee endorsed the revised draft of the VICH guideline on studies to evaluate the metabolism and residue kinetics of veterinary drugs in food-producing species: residue studies in honey, for circulation to the VICH expert working group.
- The Committee endorsed the draft EU comments on the revised VICH bioequivalence guideline following the public consultation.
- The Committee endorsed draft 3 of the VICH guideline on harmonisation of criteria to waive target animal batch safety testing for live vaccines for veterinary use and the overview of comments received, for circulation to the VICH expert working group.
- The Committee discussed the draft EU response to the VICH survey on the need for VICH guidelines for biotechnological/biological veterinary medicinal products and agreed that currently there are no ICH guidelines presenting a priority for conversion to VICH guidelines.

6.2 Codex Alimentarius

- The Committee was informed of the report on countries' needs for MRLs from the Codex Committee on residues of veterinary drugs in food (CCRVDF) electronic working group.
- The Committee was informed of the provisional agenda for the 22nd session of the Codex Committee on residues of veterinary drugs in food (CCRVDF) to be held in Costa Rica from 27 April to 1 May 2015.
- The Committee was informed of the proposed draft MRLs for consideration at the 22nd session of the Codex Committee on residues of veterinary drugs in food (CCRVDF). Draft CVMP comments on the proposed draft MRLs will be discussed at the November 2014 meeting of the Committee.

6.3 Other EU bodies and international organisations

- The Committee endorsed the organisation of the joint EMA/HMA workshop on the requirements for the authorisation of vaccines in the EU and appointed A. Holm (as CVMP representative) and E. Werner (as IWP representative) as members of the scientific steering group to the joint EMA/HMA workshop. The workshop is planned to take place in March 2015.
- The Committee noted the EFSA/WHO meeting on the threshold of toxicological concern (TTC) scheduled for 2 December 2014.

The following documents were circulated for information:

- Status of active VICH guidelines and action plan of CVMP and working parties;
- VICH Expert Working Group on Quality - Task Force on revision of GL3: revised draft concept paper on the revision of (Stability) GL3(R); EU response circulated to the Task Force;
- VICH Anthelmintic Guidelines Task Force, discussion paper and EU comments on topics 1 and 2 summarised in the discussion paper.

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 7 October 2014, and noted the agenda of the meeting.

7.2 Quality Working Party (QWP)

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 4-5 September 2014, and noted the agenda of the meeting.

7.4 Environmental Risk Assessment Working Party (ERAWP)

- The Committee adopted the revised guideline on the assessment of persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) substances in veterinary

medicines (EMA/CVMP/ERA/52740/2012), following the close of the public consultation for a second 3-month public consultation.

- The Committee discussed the draft strategy document on PBT substances.
- The Committee received a verbal update on the developments from the Council Directive 80/68/EEC, and discussed the next steps with relation to the assessment of the toxicological risk of veterinary pharmaceuticals in groundwater. It was agreed that the ERAWP and the SWP-V would be asked to work on the development of a guideline.
- The Committee discussed the revised draft reflection paper on the environmental risk assessment for avermectins used in veterinary medicines.

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 30 September – 1 October 2014, and noted the agenda of the meeting.
- The Committee endorsed the revision of the question and answer document (EMA/CVMP/414812/2011) on the CVMP guideline on the SPC for antimicrobial products concerning the definition of the terms 'treatment and prevention'. The revised document clarifies the definitions of the terms 'treatment, 'prevention' and 'metaphylaxis', and when the terms should be used for future SPCs.
- The Committee endorsed the agenda of the assessor training on bioequivalence for efficacy and quality assessors (EMA/CVMP/414708/2012) to be held on 24-25 November at EMA, London. Invitations for nominations will be sent to the Heads of Medicines Agencies shortly.
- The Committee was informed of the concept paper on the prevention of transmission of canine and feline vector-borne diseases. The adoption of the concept paper is foreseen for the November 2014 meeting of the Committee.

7.6 Antimicrobials Working Party (AWP)

- The Committee received a verbal report from the chair of the AWP on the meeting held on 24-25 September 2014, and noted the agenda of the meeting.

7.7 Immunologicals Working Party (IWP)

- The Committee received a verbal report from the chair of the IWP on the meeting held on 30 September – 1 October 2014, and noted the agenda of the meeting.
- The Committee discussed the draft guideline on data requirements for changes to the strain composition of authorised equine influenza vaccines in line with the OIE requirements and the overview of comments received. The adoption of the guideline is foreseen for the November 2014 meeting of the Committee.

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 16-17 September 2014, and noted the draft minutes of the meeting.
- The Committee was informed of the corrigendum of the CVMP combined VeDDRA list of clinical terms for reporting suspected adverse reactions in animals and humans to veterinary medicinal products, to be implemented on 1 November 2014.

7.9 Novel therapy groups and related issues

- The Committee discussed the objective and scope of the ad hoc expert group for veterinary novel therapies (ADVENT), and appointed the implementation group. Further to progress by the implementation group, the Committee would take next actions for the establishment of ADVENT at its November 2014 plenary meeting and a call for nominations for the members would be launched in November with the aim to have the ADVENT group established in December 2014.

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

The Committee discussed the draft work plans of the CVMP working parties, foreseen to be adopted at the November 2015 meeting of the Committee.

- The SAWP-V draft work plan for 2015.
- The QWP draft work plan for 2015.
- The EWP-V draft work plan for 2015.
- The IWP draft work plan for 2015.
- The AWP draft work plan for 2015.
- The SWP-V draft work plan for 2015.
- The ERAWP draft work plan for 2015.
- The JEG 3Rs draft work plan for 2015.
- The PhVWP-V draft work plan for 2015.

The following documents were circulated for information:

- Minutes of the SAWP-V meeting held on 9 September 2014;
- Final agenda of the 72st Joint CHMP/CVMP QWP meeting held on 17–19 September 2014;
- Minutes of the 71st Joint CHMP/CVMP QWP meeting held on 13–15 May 2014;
- Table of decisions of the 72st Joint CHMP/CVMP QWP meeting held on 17–19 September 2014;
- Minutes of the 58th EWP-V meeting held on 13–14 May 2014;
- Standard operating procedure (SOP/V/4042): Involvement of the CVMP Antimicrobials working party in the evaluation of applications for centralised marketing authorisations for veterinary medicinal products containing antimicrobial substances.

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 endorsed the revised template for EPMARs subject to some minor amendments to be introduced by the secretariat.
- The Committee agreed to include **cytosine-phosphate-guanine 23877** as a new entry in the list of substances considered as not falling within the scope of Regulation (EC) No 470/2009 under the heading of excipients, following the Committee's review of the request.
- The Committee noted the request for the inclusion of a substance in the list of substances considered as not falling within the scope of Regulation (EC) No 470/2009. It was agreed that, from a regulatory point of view, inclusion of this substance in the list would not be appropriate. The applicant will be informed.
- 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.23).

8.2 Environmental risk assessment

- There were no items for discussion.

8.3 Antimicrobial resistance

- The Committee received a verbal report on the ESVAC 4th annual report: Sales of veterinary antimicrobial agents in 26 EU/EEA countries in 2012.

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.

- There were no items for discussion.

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

- The Committee discussed the questions from CMDv to CVMP for scientific advice regarding the inclusion of oestrus synchronisation protocols on SPCs for consideration by the EWP-V. The Committee agreed that the questions would be forwarded to the EWP-V.
- The Committee received a verbal report from the chair of CMDv on the meeting held on 11-12 September 2014, and noted the draft agenda of the meeting held on 9-10 October 2014.

12. ORGANISATIONAL AND STRATEGIC MATTERS

- The Committee received a verbal report on the implementation of multinational assessment teams and supported the actions proposed. Further discussion will take place at the November 2014 meeting of the Committee.
- The Committee was informed of the annual report on the Agency's scientific procedures for medicinal products for human and veterinary use.
- The Committee noted the table of actions following the September 2014 CVMP meeting.

13. LEGISLATION

- There were no items for discussion.

14. ANY OTHER BUSINESS

- Upon the completion of the October 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 October 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:	• 2.1 Bovela
BE	Bruno Urbain	Full involvement	
BG	Emil Kozhuharov	Full involvement	
CZ	Jiří Bureš	Full involvement	
DE	Cornelia Ibrahim	Full involvement	
EE	Toomas Tiirats	Full involvement	
ES	Cristina Muñoz Madero	Full involvement	
FI	Irmeli Happonen	Full involvement	
HR	Ljiljana Markuš-Cizelj	No part in discussions, final deliberations and voting as appropriate, and cannot act as rapporteur for:	• 3.2 Zuprevo • 4.5 Resflor • 5.5 PSUR for Nobivac Myxo-RHD • 8.1 item
HU	Gábor Kulcsár	Full involvement	
IE	David Murphy (vice-chair)	Full involvement	
IT	Maria Tollis	Full involvement	
LU	Marc Schmit	Involvement in discussions only and cannot act as rapporteur for:	• 2.2 product • 2.5 Oncept Melanoma • 3.1 ZACTRAN • 3.3 Purevax • 5.4 Gripovac 3 • 5.5 PSURs for BTVPUR AlSap 2-4, Certifect, EQUIOXX and Previcox, Oncept IL-2 • 10.1 item
LV	Zanda Auce	Full involvement	
PT	João Pedro Duarte da Silva	Full involvement	
SE	Eva Lander Persson	Full involvement	
SI	Stane Srčič	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	Full involvement	
Co-opted	Wilhelm Schlumbohm	Full involvement	
IS	Jóhann Lenharðsson	Full involvement	
NO	Tonje Høy	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	
DK	Merete Blixenkrone-Møller	Full involvement	
EL	Angeliki Tsigouri	Full involvement	
ES	Consuelo Rubio Montejano	Full involvement	
FR	Jean-Claude Rouby	Full involvement	
NL	Peter Hekman	Full involvement	
PL	Anna Wachnik-Święcicka	Full involvement	
RO	Simona Sturzu	Full involvement	
SK	Eva Chobotová	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	Alan Fauconnier (remotely)	Full involvement	
DE	Anke Finnah (remotely)	Full involvement	
DE	Stefan Scheid (remotely)	Full involvement	
ES	Ricardo Carapeto García	Full involvement	
FR	Hélène Amar-Deguerville	Full involvement	
FR	Elisabeth Bégon (remotely)	Full involvement	
FR	Nathalie Bridoux (remotely)	Full involvement	
FR	Mathilde Harvey	Full involvement	
FR	Anne-Marie Jacques (remotely)	Full involvement	
NL	Caroline Moermond (remotely)	Full involvement	
NL	Johan Schefferlie (remotely)	Full involvement	
NL	Peter van Vlaardingen (remotely)	Full involvement	
SE	Fredrik Hultén (remotely)	Full involvement	
SE	Henrik Wahlstrom (remotely)	Full involvement	
UK	Niall O'Brian (remotely)	Full involvement	
UK	Kenneth Stapleton (remotely)	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	--
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