7 October 2014
EMA/CVMP/540437/2014
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Minutes of the 9-11 September 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 September 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.

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iv. Adoption of the minutes of the previous meeting

The minutes of the July 2014 meeting and of the August 2014 meeting by written procedure were both 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

- The Committee discussed the rapporteur's assessment report including the assessment of the responses to the list of questions, the rapporteur's EPMAR and the EU-RL report for the extension of MRLs to bovine milk for a substance (EMEA/V/MRL/003298/MODF/0004), and agreed that an oral explanation would not be necessary. The adoption of the opinion is foreseen for the October 2014 meeting of the Committee.

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

- There were no items for discussion.

2. COMMUNITY MARKETING AUTHORISATIONS AND EXTENSIONS

2.1 Opinions

- The Committee adopted by consensus (24 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **Porcilis PCV M Hyo** (EMEA/V/C/003796/0000), recommending the granting of a marketing authorisation. The product is a porcine circovirus and porcine enzootic pneumonia vaccine. 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 heard an oral explanation from the applicant, concerning an application for a new viral vaccine for cattle (EMEA/V/C/003703/0000). The Committee also discussed the draft product information and the rapporteurs' assessment of responses to the list of outstanding issues. An opinion is foreseen for the October 2014 CVMP meeting.

- 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 viral vaccine for sheep and cattle (EMEA/V/C/002781/0000). The Committee discussed the draft product

information and noted two peer review reports and the comments received from CVMP members, and agreed on the need for an oral explanation.

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 corticosteroid product for dogs (EMEA/V/C/003782/0000). The Committee noted a peer review report 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 grouped extension application for **Stronghold** (EMEA/V/C/000050/X/0051/G), to add a new strength for dogs and a new strength for cats. The Committee noted 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 viral vaccine for chickens (EMEA/V/C/003829/0000). The Committee noted a peer review report and the comments received from CVMP members.
- The Committee accepted the request from the applicant for a one-month extension to the oral explanation initially scheduled for October 2014 for a new haematological product for dogs (EMEA/V/C/002794/0000).

2.4 Re-examination of CVMP opinions

- There were no items for discussion.

2.5 Other issues

- The Committee agreed to a request from the applicant for a three-month extension to the clock stop for providing responses to the list of questions for a new psycholeptic product for dogs (EMEA/V/C/003764/0000).
- The Committee was informed of the formal notification from **MERIAL** of their decision to withdraw the application for a new marketing authorisation procedure for a new plasmid vaccine for dogs, **Oncept Melanoma** (EMEA/V/C/003684/0000). 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.
- The Committee endorsed the withdrawal EPAR, following the formal notification from the applicant to withdraw their application for a new hormonal product for cats, **Enthryv** (EMEA/V/C/002808/0000).

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

- The Committee adopted by consensus (25 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for a quality grouped worksharing type II variation for **Fevaxyn Pentofel** (EMEA/V/C/000030/WS/0489/G), recommending the variation of the marketing authorisation. The Icelandic CVMP member agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted by consensus (24 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for a quality type II variation for **STARTVAC**

(EMEA/V/C/000130/II/0002), recommending the variation of the marketing authorisation. The Icelandic CVMP member agreed with the above-mentioned recommendation of the CVMP.

- The Committee adopted by consensus (24 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for a quality grouped type II variation for **Equilis Strep E** (EMEA/V/C/000078/II/0012/G), recommending the variation of the marketing authorisation. The Icelandic CVMP member agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted by consensus (24 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for a quality type II variation for **Equilis Prequenza Te** (EMEA/V/C/000095/II/0012), recommending the variation of the marketing authorisation. The Icelandic CVMP member agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted by consensus (24 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for a quality type II variation for **Equilis Prequenza** (EMEA/V/C/000094/II/0010), recommending the variation of the marketing authorisation. The Icelandic CVMP member agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted by consensus (24 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for a quality grouped type II variation for **Hiprabovis IBR Marker Live** (EMEA/V/C/000158/II/0003/G), recommending the variation of the marketing authorisation. The Icelandic CVMP member agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted by consensus (24 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for a quality worksharing type IB variation for **Circovac, Eurican Herpes 205, Ibraxion, Purevax RCCh, Purevax RCPCh, Pyrevax RCPCh FeLV and Vaxxitek Pentofel** (EMEA/V/C/xxxx/WS/0546), recommending the variation of the marketing authorisations. The Icelandic CVMP member agreed with the above-mentioned recommendation of the CVMP.

3.2 Oral explanations and lists of outstanding issues

- The Committee adopted the CVMP list of outstanding issues for a quality grouped type II variation for **Equip WNV** (EMEA/V/C/000137/II/0018/G).

3.3 Lists of questions

- There were no items for discussion.

3.4 Re-examination of CVMP opinions

- There were no items for discussion.

3.5 Other issues

- The Committee agreed to a request from the MAH for a one-month extension to the clock stop for a type II variation for **Broadline** (EMEA/V/C/002700/II/0001) to add new indications.

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 heard an oral explanation from Ceva Santé Animale, and adopted by majority (22 members in favour out of 25 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for the referral procedure for **Suanovil 20 and associated names, Captalin and associated names and generic products thereof** (EMEA/V/A/086), recommending changes to the product information of the concerned products related to the indications, posology and withdrawal periods. The Icelandic CVMP member agreed with the above-mentioned recommendation of the CVMP. I. Happonen, K. Baptiste and M. Holzhauser-Alberti signed a divergent position regarding the conclusions on the acute clinical mastitis indication in lactating cows.

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 heard an oral explanation from MSD, and discussed the rapporteur's assessment of the responses to the list of outstanding issues including the co-rapporteur's critique for the referral procedure for **Resflor injectable solution for cattle** (EMEA/V/A/101). The adoption of the CVMP opinion is foreseen for the October 2014 meeting of the Committee.

4.6 Article 30(3) of Regulation 726/2004

- The Committee adopted the request for advice to the European Commission concerning the procedure for a scientific opinion on the risk to the consumer from the use of **lidocaine** in food-producing species (EMEA/V/A/092).

- The Committee discussed the request for an opinion from the European Commission concerning the risk to vultures and other necrophagous birds from the use of veterinary medicinal products containing **diclofenac** (EMEA/V/A/107), and appointed B. Kolar as rapporteur, and M. Holzhauser-Alberti, C. Rubio Montejano and J. Schefferlie as co-rapporteurs for the procedure. The Committee agreed to start a public consultation in order to provide stakeholders with the opportunity to input any information or data that they consider may be helpful to the CVMP in reaching its opinion. The Committee endorsed a background document on the public consultation, which was published on the Agency website requesting stakeholders to provide input by 10 October 2014. The Committee also adopted a timetable for the procedure.

4.7 Other issues

- The Committee noted the background information for publication for the Article 34 referral procedure for Baytril 2.5% injectable, Baytril 5% injectable and Baytril 10% injectable and their associated names (EMEA/V/A/091).

- The Committee noted the background information for publication for the Article 35 referral procedure for Baytril 2.5% injectable, Baytril 5% injectable, Baytril 10% injectable and associated names, and related veterinary medicinal products (EMEA/V/A/097).

- The Committee noted the background information for publication for the Article 35 referral procedure for veterinary medicinal products containing tylosin to be administered orally via feed or the drinking water to pigs (EMEA/V/A/100).

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

5.1 General issues

Information relating to topics discussed under point 5.1 at this meeting cannot be released at the present time as it is deemed to be confidential.

5.2 Post-authorisation measures and annual reassessments

- The Committee adopted the list of questions for the annual reassessment of **COXEVAC** (EMEA/V/C/000155/S/0007).
- The Committee endorsed the rapporteur's assessment report regarding the marketing authorisation holder's response to the CVMP recommendation to provide comparative stability data for **ZOLVIX** (EMEA/V/C/000154/REC/025) and concluded that the data for the recommendation are satisfactory.

5.3 Product anniversary list

- The Committee endorsed the product anniversary list for the period between 12.07.2014 – 09.09.2014:

Product	Period
Nobilis Influenza H5N2 (EMEA/V/C/000118)	01.09.2013 – 31.08.2014
Nobivac Bb for Cats (EMEA/V/C/000068)	10.09.2013 – 09.09.2014
Nobivac L4 (EMEA/V/C/002010)	16.07.2013 – 15.07.2014
Nobivac Myxo-RHD (EMEA/V/C/002004)	07.09.2013 – 06.09.2014
Previcox (EMEA/V/C/000082)	10.09.2013 – 09.09.2014
Profender (EMEA/V/C/000097)	27.07.2013 – 26.07.2014
Proteq West Nile (EMEA/V/C/002005)	05.08.2013 – 04.08.2014
ProZinc (EMEA/V/C/002634)	12.07.2013 – 11.07.2014
Suvaxyn Aujeszky 783 o/w (EMEA/V/C/000038)	07.08.2013 – 06.08.2014
Suvaxyn PCV (EMEA/V/C/000149)	24.07.2013 – 23.07.2014
Trocoxil (EMEA/V/C/000132)	09.09.2013 – 08.09.2014
Vaxxitek HVT+IBD (EMEA/V/C/000065)	09.08.2013 – 08.08.2014
ZACTRAN (EMEA/V/C/000129)	24.07.2013 – 23.07.2014
Zulvac 1 Bovis (EMEA/V/C/002334)	05.08.2013 – 04.08.2014
Zulvac 1 Ovis (EMEA/V/C/002335)	05.08.2013 – 04.08.2014

5.4 Renewals

- The Committee adopted a list of outstanding issues for the renewal of **Respiporc Flu3** (EMEA/V/C/000153/R/0006).
- The Committee adopted by consensus (25 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for the renewal of **ZOLVIX**

(EMEA/V/C/000154/R/0013), and agreed that the authorisation should now be indefinite. The Icelandic CVMP member agreed with the above-mentioned recommendation of the CVMP.

- The Committee adopted a list of outstanding issues for the renewal of **Gripovac 3** (EMEA/V/C/000157/R/0005).
- The Committee adopted by consensus (24 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for the renewal of **Zulvac 8 Bovis** (EMEA/V/C/000145/R/0016), and agreed that the authorisation should now be indefinite. The Icelandic CVMP member agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted by consensus (24 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for the renewal of **Zulvac 8 Ovis** (EMEA/V/C/000147/R/0016), and agreed 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 PSUR for the period 01.08.13-31.01.14 for **Activyl Tick Plus** (EMEA/V/C/002234) with a recommendation to amend section 4.6 of the product literature.
- 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
Flexicam (EMEA/V/C/000102)	01.05.2011-30.04.2014
Meloxoral (EMEA/V/C/000151)	19.05.2013-19.05.2014
Porcilis AR-T DF (EMEA/V/C/000055)	01.06.2013-31.05.2014
Suvaxyn PCV (EMEA/V/C/000149)	01.08.2013-31.01.2014
ZOLVIX (EMEA/V/C/000154)	01.05.2013-30.04.2014

- The Committee endorsed the list of products and calendar for signal detection analysis.
- The Committee noted an article by the Veterinary Medicines Directorate (VMD-UK) to veterinary surgeons concerning advice on the use of **Pexion** (EMEA/V/C/002543), for publication in the Veterinary Record.

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 guideline on studies to evaluate the safety of residues of veterinary drugs in human food: general approach to establish an acute reference dose (ARfD) for sign-off at step 2 of the VICH process.

- The Committee endorsed the draft revision of VICH GL48 on studies to evaluate the metabolism and residue kinetics of veterinary drugs in food-producing animals: marker residue depletion studies to establish withdrawal periods, as well as the draft revision of VICH GL49 on studies to evaluate the metabolism and residue kinetics of veterinary drugs in food-producing animals: validation of analytical methods used in residue depletion studies, both for sign-off at step 5/6 of the VICH process.
- The Committee endorsed the draft EU comments on the revised draft concept paper on the revision of VICH Stability GL3(R).
- The Committee endorsed the revised VICH GL23 guideline on genotoxicity testing for sign-off at step 6 of the VICH process and noted the comments received during public consultation.
- The Committee received a report on the VICH Expert Working Group on Metabolism and Residue Kinetics meeting held on 16-19 June 2014 in Brussels, and discussed the latest revisions of the draft guideline on residue studies in honey and the draft guideline on residue studies in fish, both at step 2 of the VICH process.
- The Committee discussed the VICH survey on the need for VICH GLs for biotechnological/biological veterinary medicinal products. The Committee agreed that both QWP and IWP would be consulted.
- The Committee noted the revised draft guideline on electronic exchange of documents: electronic file formats (EFF) and the compilation of comments from the regions.

6.2 Codex Alimentarius

- There were no items for discussion.

6.3 Other EU bodies and international organisations

Information relating to topics discussed under point 6.3 at this meeting 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 received a verbal report from the acting chair of the SAWP-V on the meeting held on 9 September 2014, and noted the agenda of the meeting.

7.2 Quality Working Party (QWP)

- The Committee noted the election by the CHMP (at their July meeting) of Keith Pugh as the Human vice chairperson of the Joint CHMP/CVMP Quality Working Party, for a 3 year term.

7.3 Safety Working Party (SWP-V)

- The Committee adopted the guideline on setting health based exposure limits for use in risk identification in the manufacture of different medicinal products in shared facilities.

- The Committee noted the comments received from IFAH-Europe and EGGVP during the public consultation on the concept paper for a guideline on user safety of topically administered products, and confirmed that the working party should develop a guideline on this topic.

7.4 Environmental Risk Assessment Working Party (ERAWP)

- The Committee discussed the revised draft guideline on the assessment of persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) substances in veterinary medicinal products and supported a second public consultation considering the number of amendments made. The revised draft guideline is intended to be adopted at the October or November CVMP meeting.
- The Committee discussed the revised draft CVMP reflection paper on the environmental risk assessment for avermectins used in veterinary medicines.
- The Committee discussed the draft strategy for the consideration of veterinary medicinal products containing (potential) PBT substances.

7.5 Efficacy Working Party (EWP-V)

- The Committee discussed the overview of comments received from interested parties on the draft reflection paper on anthelmintic resistance and the overview of the FDA's public meeting on antiparasitic drug use and resistance in ruminants and equines held in 2012.

7.6 Antimicrobials Working Part (AWP)

- There were no items for discussion.

7.7 Immunologicals Working Part (IWP)

- The Committee agreed for IWP to provide EDQM with their comments on the revised chapter 5.2.4 taking into account the comments received during the public enquiry in Pharmaeuropa 25.4, as a follow-up to the ad hoc meeting on the risk management strategy in relation to RD114.
- The Committee noted the letter received from EDQM on pharmaceutical containers and closures.

7.8 Pharmacovigilance Working Party (PhVWP-V)

- The Committee endorsed the overview of comments received on the review of the recommendation on pharmacovigilance surveillance and signal detection on veterinary medicinal products, following the end of the public consultation.
- The Committee noted the draft agenda of the meeting of the Focus Group on signal detection, scheduled for 19 November 2014.

7.9 Novel therapy groups and related issues

7.10 Joint CVMP/CHMP AHEG on the application of the 3Rs

- The Committee noted the comments received from interested parties during the public consultation on the concept paper on review and update of EMA guidelines to implement best practice with regard to 3Rs and confirmed that relevant guidelines should be updated as proposed in the concept paper.
- The Committee adopted the guideline on regulatory acceptance of 3Rs testing approaches. The guideline will be published for consultation following its adoption by CHMP.

- The Committee indicated its support for the extension of the mandate (EMA/544352/2014) of the JEG 3Rs group for further two years.

7.11 Other working party and scientific group issues

- The Committee considered the options for access to CVMP working parties documentation in the electronic system for managing meeting documents (MMD) which at present is being implemented for SWP-V, IWP and SAWP-V, and agreed that the CVMP delegates will have full access by default to the meeting documentation of all its working parties, but they will not receive any notifications of when the meeting documents are circulated.

The following documents were circulated for information:

- Minutes of the SAWP-V meeting held on 8 July 2014;
- Draft agenda for QWP meeting to be held 17-19 September 2014;
- Draft agenda for QWP Assessor training to be held 14-15 October 2014;
- Draft agenda for EWP meeting to be held 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 considered requests for inclusion of three excipients in the list of substances considered as not falling within the scope of Regulation (EC) No 470/2009 and agreed to include **isotridecanol ethoxylates** and **vanillin** in the list. The Committee considered that a more in-depth review would be needed for the third request and so recommended that the applicant consider submitting a scientific advice request.
- 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.22).
- The Committee reviewed a request for clarification in relation to the MRL status for **2-pyrrolidone**, and confirmed that the restriction in Commission Regulation (EU) No 37/2010 should be interpreted as meaning that the substance can be given by any route but that a maximum dose of 40 mg/kg bw applies when administered parenterally.
- The Committee discussed the comments received during the public consultation on the reflection paper on injection site residues and agreed to ask the Commission to coordinate further dialogue with residue control authorities.

8.2 Environmental risk assessment

- There were no items for discussion.

8.3 Antimicrobial resistance

- There were no items for discussion.

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 discussed the concept paper for the review of the MUMS guidelines on data requirements for veterinary medicinal products for minor use minor species. It was agreed that the concept paper would be sent to the relevant working parties for their review and recommendations. The adoption of the concept paper is foreseen for the November 2014 meeting of the Committee.

9. AVAILABLITY OF MEDICINES AND MUMS CLASSIFICATION

Information relating to availability of medicines cannot be released at the present time as it is deemed to be commercially confidential.

- The Committee endorsed a draft guidance document on the classification of veterinary medicinal products indicated for MUMS/limited market (EMA/CVMP/388694/2014) for a 6 week period of public consultation. This document gives guidance for implementing the updated policy (EMA/308411/2014), which states the objectives of the MUMS/limited market policy, and updates the previous guidance given in document EMA/429080/2009-Rev.1.

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.

- The Committee endorsed the EPAR module 6 scientific discussion for **ERYSENG** (EMEA/V/C/002761/0000) concerning the granting of the initial marketing authorisation.
- The Committee endorsed the EPAR module 6 scientific discussion for **ERYSENG PARVO** (EMEA/V/C/002762/0000) concerning the granting of the initial marketing authorisation.

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

- The Committee received a verbal report from E. Werner on the CMDv meeting held on 10-11 July 2014, and noted the draft minutes of the meeting as well as the draft agenda of the meeting held on 11-12 September 2014. The Committee welcomed the new chair of CMDv, Gavin Hall, whose 3-year mandate started on 11 September 2014.

12. ORGANISATIONAL AND STRATEGIC MATTERS

- The Committee adopted the agenda of the CVMP Presidency meeting, including the agenda of the joint CVMP/CMDv Presidency meeting, to be held on 22-23 September in Rome, Italy.
- The Committee received a verbal report from the chair of the Strategic Planning Group on the meeting dedicated to the Agency's road map, held on 10 September 2014, and noted the agenda of the meeting and the minutes of the meeting held on 4 June 2014. The CVMP chair

will circulate the draft text on the Agency's road map for 2015-2020 to CVMP members for their comments.

- The Committee noted the CVMP dates for 2015.
- The Committee noted the table of actions following the July 2014 CVMP meeting.

13. LEGISLATION

- The Committee was informed of the publication of the Commission proposal for the revision of the legal framework for veterinary medicinal products.

14. ANY OTHER BUSINESS

- Upon the completion of the September 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 September 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:	• 2.2 - EMEA/V/C/003703/0000 • 9. - product
BE	Bruno Urbain	Full involvement	
BG	Emil Kozhuharov	Full involvement	
CZ	Jiří Bureš	Full involvement	
DK	Ellen-Margrethe Vestergaard	Full involvement	
EL	Ioannis Malemis	Full involvement	
ES	Cristina Muñoz Madero	Full involvement	
FI	Irmeli Happonen	Full involvement	
FR	Michael Holzhauser-Alberti	Full involvement	
HU	Gábor Kulcsár	Full involvement	
IE	David Murphy (vice-chair)	Full involvement	
IT	Maria Tollis	Full involvement	
LV	Zanda Auce	Full involvement	
NL	Johan Schefferlie	Full involvement	
RO	Lollita Taban	Full involvement	
SE	Eva Lander Persson	Full involvement	
SK	Judita Hederova	Full involvement	
UK	Helen Jukes	Full involvement	
Co-opted	Keith Baptiste	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	

Country	CVMP Alternate	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
BE	Frederic Klein	Full involvement	
DE	Esther Werner	Full involvement	
ES	Consuelo Rubio Montejano	Full involvement	
FR	Jean-Claude Rouby	Full involvement	
HR	Frane Bozic	Full involvement	
PL	Anna Wachnik-Święcicka	Cannot act as rapporteur or peer reviewer for:	• 10.1 – product

Country	CVMP Alternate	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
PT	Maria Azevedo Mendes	Full involvement	
UK	Anna-Maria Brady	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	Koen Brusselmans *(remotely)*	Full involvement	
ES	Javier Martínez de Velasco	Full involvement	
FR	Nathalie Bridoux *(remotely)*	Full involvement	
FR	Sylvie Louet *(remotely)*	Full involvement	
UK	Rutendo Manyarara	Full involvement	
UK	Javier Pozo	Full involvement	

CVMP working parties and CMDv	Chair
AWP	Helen Jukes
CMDv	Gavin Hall
ERAWP	Boris Kolar
EWP	Gesine Hahn
IWP	Esther Werner
PhVWP	--
QWP	Piet-Hein Overhaus *(Vet vice chair - remotely)*
SAWP	--

Observer from the European Commission	
Present	

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