6 October 2015
EMA/CVMP/661152/2015
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Minutes of the 8-10 September 2015 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 two new items under points 7.1 and 8.5.

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

The attendance list was completed and interests were identified for the September 2015 meeting. In accordance with the Agency's revised policy and procedure on the handling of declarations of interests, participants in this meeting were asked to declare any interests on the matters for discussion (in particular any changes, omissions or errors to the already declared interests). Discussions, deliberations and voting took place in full respect of the restricted involvement of Scientific Committee members and, where relevant, experts attending the plenary meeting, as announced by the Scientific Committee Secretariat at the start of the meeting (see Annex I). All decisions taken at this meeting were made in presence of a quorum of members i.e. 22 or more members were present in the room. It was noted that 17 members were needed for an absolute majority.

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

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

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No contacts were declared.

iv. Adoption of the minutes of the previous meeting

The minutes of the July 2015 meeting and of the August 2015 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

- 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 rapporteur's proposal for an EPMAR for the extrapolation of the MRLs for a substance (EMEA/V/MRL/003669/EXPL/0002). The opinion is foreseen to be adopted at the October meeting of the Committee.
- The Committee agreed to the request from the applicant to delay the submission of the responses to the list of outstanding issues for the establishment of MRLs in bovine species for a substance (EMEA/V/MRL/002993/FULL/0002).

2. COMMUNITY MARKETING AUTHORISATIONS AND EXTENSIONS

2.1 Opinions

- The Committee adopted by consensus (28 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **Zycortal** (EMEA/V/C/003782/0000), recommending the granting of a marketing authorisation. The product is a new mineralocorticoid corticosteroid prolonged-release suspension for injection containing desoxycortone pivalate, for use as replacement therapy for mineralocorticoid deficiency in dogs with primary hypoadrenocorticism (Addison's disease). 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 product is classified as MUMS/limited market.
- The Committee adopted by consensus (28 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **Simparica**

(EMEA/V/C/003991/0000) chewable tablets, recommending the granting of a marketing authorisation. The product is a new ectoparasiticide for oral use in dogs for the treatment of flea, tick and sarcoptic mange infestations. 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 (27 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **Suvaxyn Circo+MH RTU** (EMEA/V/C/003924/0000), recommending the granting of a marketing authorisation. The product is a new inactivated viral and bacterial vaccine for pigs, against porcine circovirus type 2 and *Mycoplasma hyopneumoniae* infection. 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 hormonal product for cattle (EMEA/V/C/002590/0000). The Committee also discussed the draft product information and the draft CVMP assessment report. An opinion is foreseen for the October 2015 CVMP meeting.
- The Committee heard an oral explanation from the applicant concerning an application for a new product (EMEA/V/C/002763/0000), for the treatment of mastitis in cattle. The Committee also discussed the draft product information and the draft CVMP assessment report. An opinion is foreseen for the October 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 **Bravecto** (EMEA/V/C/002526/X/0005), to add a new pharmaceutical form. The Committee agreed that an oral explanation will not be requested. 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 list of participants for the AHEG meeting to be held on 21-22 September 2015 concerning an application for a new product (EMEA/V/C/002390/0000), a new vaccine for Atlantic salmon.
- The Committee endorsed the EPAR module 6 scientific discussion for **Porcilis PCV ID** (EMEA/V/C/003942/0000) concerning the granting of the initial marketing authorisation.
- The Committee endorsed the EPAR module 6 scientific discussion for **Vectormune ND** (EMEA/V/C/003829/0000) concerning the granting of the initial marketing authorisation.
- The Committee endorsed the EPAR module 6 scientific discussion for **FORTEKOR PLUS** (EMEA/V/C/002804/0000) concerning the granting of the initial marketing authorisation.
- The Committee endorsed the EPAR module 6 scientific discussion for **Novaquin** (EMEA/V/C/003866/0000) concerning the granting of the initial marketing authorisation.

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 quality, worksharing type IB variation for **Circovac**, **Eurican Herpes 205**, **Ibraxion**, **Purevax RCPCh FeLV** and **Purevax RCPCh** (EMEA/V/C/xxxxxx/WS/0774), recommending the variation of the marketing authorisations. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP.

- The Committee adopted by consensus (28 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for a quality type II variation for **RESPIPORC FLU3** (EMEA/V/C/000153/II/0010), 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 (28 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for a quality type II variation for **Gripovac 3** (EMEA/V/C/000157/II/0008), 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 (28 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for a type II variation for **SevoFlo** (EMEA/V/C/000072/II/0016), 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 (28 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for a quality type II variation for **Ingelvac CircoFLEX** (EMEA/V/C/000126/II/0020), 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 (28 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for a quality grouped type II variation for **Aivlosin** (EMEA/V/C/000083/II/0062/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 (28 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for a quality worksharing type II variation for **NexGard** and **NEXGARD SPECTRA** (EMEA/V/C/xxxxxx/WS/0756), recommending the variation of the marketing authorisations. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP.

- The Committee adopted by consensus (28 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for a grouped type II variation for **ZULVAC SBV** (EMEA/V/C/002781/II/0002/G), recommending the variation of the marketing authorisation to change the vaccination schedule and to extend the duration of immunity. The

Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP.

- The Committee adopted by consensus (28 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for a quality grouped worksharing type II variation for **Versican Plus DHPPi/L4R**, **Versican Plus Pi/L4R**, **Versican Plus Pi/L4**, **Versican Plus DHPPi/L4**, **Versican Plus DHPPi** and **Versican Plus Pi** (EMEA/V/C/xxxxxx/WS/0753/G), recommending the variation of the marketing authorisations. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP.

- The Committee adopted by consensus (28 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for a quality type II variation for **Eurican Herpes 205** (EMEA/V/C/000059/II/0017), 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 (28 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for a quality grouped type II variation for **STARTVAC** (EMEA/V/C/000130/II/0003/G), recommending the variation of the marketing. 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 November 2015 for a type II variation for **DRAXXIN** (EMEA/V/C/000077/II/0031), to add a new indication.

3.3 Lists of questions

- The Committee adopted the list of questions for a quality type II variation for **Porcilis PCV M Hyo** (EMEA/V/C/003796/II/0003).

- The Committee adopted the list of questions for a quality grouped worksharing type II variation for **Versican Plus DHPPi/L4**, **Versican Plus DHPPi/L4R**, **Versican Plus Pi/L4R**, **Versican Plus DHPPi**, **Versican Plus Pi** and **Versican Plus Pi/L4** (EMEA/V/C/xxxxxx/WS/0754/G).

3.4 Re-examination of CVMP opinions

- There were no items for discussion.

3.5 Other issues

- There were no items for discussion.

4. REFERRALS AND RELATED PROCEDURES

4.1 Article 33 of Directive 2001/82/EC

- There were no items for discussion.

4.2 Article 34 of Directive 2001/82/EC

- The Committee considered the notification and its annex from Germany, for a referral procedure for **Denagard 45% and associated names** concerning the harmonisation of the product information. The Committee agreed to start a referral procedure (EMEA/V/A/114) under Article 34 and appointed C. Ibrahim as rapporteur and C. Muñoz as co-rapporteur for the procedure. The Committee adopted a list of questions and a timetable, and noted the list of products concerned. The adoption of the opinion is foreseen for the April 2016 meeting of the Committee.

4.3 Article 35 of Directive 2001/82/EC

- There were no items for discussion.

4.4 Article 78 of Directive 2001/82/EC

- The Committee heard an oral explanation from the marketing authorisation holder, Norbrook Laboratories Ltd, and discussed the rapporteur's assessment report including the critique from the co-rapporteur for the procedure for **Closamectin pour-on solution and associated names** (EMEA/V/A/113). The Committee noted four peer review reports. The adoption of the opinion is foreseen for the October 2015 meeting of the Committee.

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

- There were no items for discussion.

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

- There were no items for discussion.

4.7 Other issues

Information relating to certain topics discussed under section 4.7 at this meeting cannot be released at the present time as it is deemed to be confidential.

The following document was circulated for information:

- Coglapix suspension for injection for pigs - Article 33(4) referral (EMEA/V/A/109) – Questions and answers for publication (EMA/589476/2015)

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

5.1 General issues

- There were no items for discussion.

5.2 Post-authorisation measures and annual reassessments

- The Committee adopted the rapporteur's assessment report on the data submitted concerning a recommendation for **Equip WNV** (EMEA/V/C/000137/REC/022).
- The Committee adopted the rapporteur's assessment report on the data submitted concerning a condition for **Nobilis IB Primo QX** (EMEA/V/C/002802/ANX/001).

5.3 Product anniversary list

- The Committee endorsed the product anniversary list for the period between 10.07.2015 – 10.09.2015:

Product	Period
AFTOVAXPUR DOE (EMEA/V/C/002292)	15/07/2014 – 14/07/2015
Aivlosin (EMEA/V/C/000083)	09/09/2014 – 08/09/2015
Bovilis BTV8 (EMEA/V/C/000148)	06/09/2014 – 05/09/2015
Cardalis (EMEA/V/C/002524)	23/07/2014 – 22/07/2015
Dexdomitor (EMEA/V/C/000070)	30/08/2014 – 29/08/2015
Emdocam (EMEA/V/C/002283)	18/08/2014 – 17/08/2015
Nobilis IB Primo QX (EMEA/V/C/002802)	04/09/2014 – 03/09/2015
Nobilis Influenza H5N2 (EMEA/V/C/000118)	01/09/2014 – 31/08/2015
Nobivac Bb for cats (EMEA/V/C/000068)	10/09/2014 – 09/09/2015
Nobivac L4 (EMEA/V/C/002010)	16/07/2014 – 15/07/2015
Nobivac Myxo-RHD (EMEA/V/C/002004)	07/09/2014 – 08/09/2015
OSURNIA (EMEA/V/C/003753)	31/07/2014 – 30/07/2015
Profender (EMEA/V/C/000097)	27/07/2014 – 26/07/2015
Proteq West Nile (EMEA/V/C/002005)	05/08/2014 – 04/08/2015
ProZinc (EMEA/V/C/002634)	12/07/2014 – 11/07/2015
Suprelorin (EMEA/V/C/000109)	10/07/2014 – 09/07/2015
Suvaxyn Aujeszky 783 + O/W (EMEA/V/C/000038)	07/08/2014 – 06/08/2015
Suvaxyn PCV (EMEA/V/C/000149)	24/07/2014 – 23/07/2015
Trocoxil (EMEA/V/C/000132)	09/09/2014 – 08/09/2015
Vaxxitek HVT+IBD (EMEA/V/C/000065)	09/08/2014 – 08/08/2015
Versican Plus L4 (EMEA/V/C/003680)	31/07/2014 – 30/07/2015
Versican Plus Pi/L4 (EMEA/V/C/003683)	31/07/2014 – 30/07/2015
Versican Plus Pi/L4R (EMEA/V/C/003682)	31/07/2014 – 30/07/2015
ZACTRAN (EMEA/V/C/000129)	24/07/2014 – 23/07/2015
ZULVAC 1 Bovis (EMEA/V/C/002334)	05/08/2014 – 04/08/2015
ZULVAC 1 Ovis (EMEA/V/C/002335)	05/08/2014 – 04/08/2015

5.4 Renewals

- The Committee adopted by consensus (28 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for the renewal of **Hiprabovis IBR Marker Live** (EMEA/V/C/000158/R/0007), and agreed that the authorisation should now be indefinite. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted the list of outstanding issues for the renewal of **Cimalgex** (EMEA/V/C/000162/R/0002).

5.5 Pharmacovigilance – PSURs and SARs

- The Committee adopted the CVMP assessment of the final study report on a post authorization safety study for **Parvoduk** (EMEA/V/C/002740) with a recommendation to amend the SPC.
- The Committee discussed the request from MSD Animal Health to reconsider the recommendation of the outcome of the PSUR for the period 01.08.2014 – 31.01.2015 for **Nobivac L4** (EMEA/V/C/002010), and confirmed the wording of the required SPC amendment adopted at the July CVMP.
- 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**
Fungitraxx (EMEA/V/C/002722)	01.10.2014 – 31.03.2015
Meloxidolor (EMEA/V/C/002590)	22.10.2014 – 22.04.2015
Meloxoral (EMEA/V/C/000151)	19.05.2014 – 19.05.2015
Nobilis IB4-91 (EMEA/V/C/000036)	01.10.2013 – 31.03.2015
Parvoduk (EMEA/V/C/002740)	01.11.2014 – 30.04.2015
Porcilis AR-T DF (EMEA/V/C/000055)	01.06.2014 – 31.05.2015
Porcilis PCV M Hyo (EMEA/V/C/003796)	07.11.2014 – 31.05.2015
Recuvyra (EMEA/V/C/002239)	01.11.2014 – 30.04.2015
Versican Plus DHPPi/L4 (EMEA/V/C/003678)	01.12.2014 – 31.05.2015
Versican Plus DHPPi/L4R (EMEA/V/C/002759)	01.12.2014 – 31.05.2015

- 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 adopted the VICH guideline 52 on Bioequivalence: blood level bioequivalence study, following the sign-off by the VICH Steering Committee, for implementation in the EU at step 7 of the VICH process by 31 August 2016. As a consequence of this new bioequivalence guideline, the respective CVMP guideline on the "Conduct of bioequivalence studies for veterinary medicinal products" (CVMP/016/2000 Rev. 2) will be revised accordingly.

6.2 Codex Alimentarius

- There were no items for discussion.

6.3 Other EU bodies and international organisations

The following documents were circulated for information:

- Status of active VICH guidelines and action plan of CVMP and working parties;
- Draft programme for VICH 5th Conference to be held in Tokyo, 27-29 October 2015;
- Revised standard operating procedure SOP/V/4047 on the Review and Approval of VICH Guidelines by CVMP and its WPs – minor editorial changes only, no change in procedure.

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 8 September 2015, and noted the agenda of the meeting.

7.2 Quality Working Party (QWP)

- The Committee adopted the revised question and answer document on complex manufacturing processes.

7.3 Safety Working Party (SWP-V)

7.4 Environmental Risk Assessment Working Party (ERAWP)

- The Committee adopted the guideline on the assessment of persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) substances in veterinary medicinal products (EMA/CVMP/ERA/52740/2015) and the overview of comments received during the second public consultation (EMA/CVMP/ERA/74265/2015).

7.5 Efficacy Working Party (EWP-V)

- There were no items for discussion.

7.6 Antimicrobials Working Party (AWP)

- There were no items for discussion.

7.7 Immunologicals Working Party (IWP)

- The Committee adopted the guideline on the procedure to be followed when a batch of a vaccine finished product is suspected to be contaminated with bovine viral diarrhoea virus (EMA/CVMP/IWP/205351/2006-Rev.1), and the overview of comments received during the public consultation (EMA/CVMP/IWP/342158/2015).
- The Committee adopted the reflection paper on the use of heat treatment to inactivate endogenous retroviruses in live immunological veterinary medicinal products (EMA/CVMP/IWP/37924/2014), and the overview of comments received during the public consultation (EMA/CVMP/IWP/254504/2015).
- The Committee adopted the reflection paper on the replacement of cell lines used for the production of immunological veterinary medicinal products (EMA/CVMP/IWP/37620/2014), and the overview of comments received during the public consultation (EMA/CVMP/IWP/254498/2015).
- The Committee adopted the concept paper on requirements for the production and control of allergen products for use in animals (EMA/CVMP/IWP/351882/2015) for a 3-month period of public consultation.

7.8 Pharmacovigilance Working Party (PhVWP-V)

- There were no items for discussion.

7.9 Novel therapy groups and related issues

- There were no items for discussion.

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

7.11 Other working party and scientific group issues

- There were no items for discussion.

The following documents were circulated for information:

- Minutes of the SAWP-V meeting held on 7 July 2015;
- Draft agenda of the 76th Joint CHMP/CVMP QWP meeting to be held on 30 September to 2 October 2015; draft agenda of the Joint QWP/GMDP IWG meeting to be held on 2 October 2015;
- Draft agenda of the EWP meeting to be held on 15–16 September 2015;
- Draft agenda of AWP meeting to be held on 23-24 September 2015;
- Minutes from PhVWP meeting held on 30 June and 1 July 2015;
- Draft programme for EPAA annual conference on 1 December 2015.

8. OTHER SCIENTIFIC MATTERS

8.1 MRLs issues

Information on certain MRL related issues cannot be released at the present time as it is deemed to be confidential.

8.2 Environmental risk assessment

Information on certain environmental risk assessment related issues cannot be released at the present time as it is deemed to be confidential.

8.3 Antimicrobial resistance

- The Committee received an update on the Joint EFSA/EMA scientific opinion on measures to reduce the need to use antimicrobial agents in animal husbandry in the European Union, and the resulting impacts on food safety.

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.

9. AVAILABILITY OF MEDICINES AND MUMS CLASSIFICATION

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

10. PROCEDURAL AND REGULATORY MATTERS

10.1 Eligibility and appointment of rapporteurs, co-rapporteurs and peer reviewers

Information relating to notification of intent for new MRL applications and notification of intent and eligibility requests for Community marketing authorisations cannot be released at the present time as it is deemed to be commercially confidential.

- The Committee agreed to the transfer of all (co-)rapporteurship and peer reviewer responsibilities from M. Holzhauser-Alberti to J.-C. Rouby.

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 on the meeting held on 9-10 July 2015, and noted the draft minutes of the meeting as well as the draft agenda of the meeting held on 10-11 September 2015.

12. ORGANISATIONAL AND STRATEGIC MATTERS

- The Committee discussed and adopted the agenda of the CVMP Presidency meeting and the agenda of the joint CVMP/CMDv Presidency meeting, to be held on 21-22 September 2015 in Luxembourg.
- The Committee reviewed the comments received on the draft guideline on the principles for preparing assessment reports for veterinary medicinal products and the draft guidance template for preparing the scientific overview for pharmaceuticals and discussed the process for finalising the documents.
- The Committee received a verbal report from the Chair of CVMP on the CVMP questionnaire on the functioning of the Committee.
- The Committee received a verbal report from the Chair of CVMP on the meeting of the Scientific Coordination Board held on 29 June 2015 and noted the agenda of the meeting.
- The Committee received an update on recent confidentiality arrangements with third country regulators and organisations.
- The Committee was informed of the remaining activities of the EMA 20th Anniversary programme.
- The Committee noted the table of actions following the July 2015 CVMP meeting.

13. LEGISLATION

- There were no items for discussion.

14. ANY OTHER BUSINESS

- Upon the completion of the September 2015 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 2015 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 Ingelvac CircoFLEX (EMEA/V/C/000126/II/0020)
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	
EL	Ioannis Malemis	Full involvement	
ES	Cristina Muñoz Madero	Full involvement	
FR	Jean-Claude Rouby	Full involvement	
HR	Ljiljana Markuš-Cizelj	Full involvement	
IE	David Murphy (vice-chair)	Full involvement	
IT	Maria Tollis	Full involvement	
LU	Marc Schmit	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	
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	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
DE	Esther Werner	Full involvement	
DK	Merete Blixenkrone-Møller	Full involvement	
ES	Consuelo Rubio Montejano	Cannot act as rapporteur or peer reviewer for:	• 2.2 EMEA/V/C/002763 • 2.2 Bravecto (EMEA/V/C/002526/X/0005)

Country	CVMP Alternate	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
			• 3.1 Gripovac 3 (EMEA/V/C/000157/II/0008) • 3.1 RESPIPORC FLU3 (EMEA/V/C/000153/II/0010) • 3.3 Porcilis PCV M Hyo (EMEA/V/C/003796/II/0003) • 5.2 Nobilis IB Primo QX (EMEA/V/C/002802/ANX/001) • 5.5 PSURs for Nobilis IB4-91, Nobivac L4, Porcilis AR-T DF, Porcilis PCV M Hyo
HU	Tibor Soós	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	Gerd Maack *(remotely)*	Full involvement	
ES	Miguel Escribano *(remotely)*	Full involvement	
FR	Elisabeth Begon	Full involvement	
FR	Sylvie Louet	Full involvement	
NL	Sandra Ten Voorde *(remotely)*	Full involvement	
SE	Carina Bergman *(remotely)*	Full involvement	
SE	Fredrik Hulten *(remotely)*	Full involvement	
UK	Giles Davis	Full involvement	
UK	Gillian Diesel *(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

CVMP working parties and CMDv	Chair
PhVWP-V	--
QWP	--
SAWP-V	Rory Breathnach
SWP-V	--

Observer from the European Commission	
Present	

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