2 June 2015
EMA/CVMP/368443/2015
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Minutes of the 5-7 May 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 no modifications.

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

The attendance list was completed and interests were identified for the May 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 the 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 April 2015 meeting were adopted with no amendments.

v. Topics for rapporteur's meetings, break-out sessions and oral explanations

Information relating to briefing meetings taking place with applicants cannot be released at the present time as it is deemed to be commercially confidential.

1. ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS

1.1 Opinions

- The Committee adopted by consensus (31 members present of those eligible to vote) the CVMP opinion including the EPMAR recommending the modification of the current entry in Table 1 (Allowed substances) of the Annex to Commission Regulation (EC) No 37/2010 for **diflubenzuron** in *Salmonidae* (EMEA/V/MRL/003135/MODF/0003), amending the existing MRL to a provisional one, pending provision of additional residue data. The recommendation followed a request from the European Commission under Article 11 of Regulation (EC) No 470/2009 for the review of the MRLs for diflubenzuron. 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 majority (30 members in favour out of the 31 members present of those eligible to vote) the CVMP opinion including the EPMAR and the CVMP assessment report, recommending the inclusion of **purified semi-solid extract from *Humulus lupulus L.* containing approximately 48% of beta acids (as potassium salts)** (EMEA/V/MRL/003923/FULL/0001) in Table 1 (Allowed substances) of the Annex to Commission Regulation (EC) No 37/2010 with a "No MRL required" classification in honey. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP. C. Friis signed a divergent position not supporting the aforementioned recommendation. The Committee noted the comments from EFSA and the summary of opinion for publication.

1.2 Oral explanations and lists of outstanding issues

- There were no items for discussion.

1.3 Lists of questions

- There were no items for discussion.

1.4 Re-examination of CVMP opinions

- The Committee adopted by consensus (29 members present of those eligible to vote) the final CVMP opinion including the EPMAR and the final CVMP assessment report revising its previous recommendation for the establishment of MRLs in bovine and caprine species for **sisapronil** (EMEA/V/MRL/003915/FULL/0001). The final CVMP opinion followed a request from the applicant for the re-examination of the CVMP opinion of 15 January 2015. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP. The Committee noted the summary of opinion for publication.

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 **Innovax-ILT** (EMEA/V/C/003869/0000), recommending the granting of a marketing authorisation. The product is a new viral vaccine against infectious laryngotracheitis and Marek's disease in chickens. 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 (29 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **Canigen L4** (EMEA/V/C/004079/0000), recommending the granting of a marketing authorisation. The product is a new bacterial vaccine for active immunisation of dogs against *Leptospira*. 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 product for the treatment of mastitis in cattle (EMEA/V/C/002763/0000). The Committee agreed to invite the applicant for an oral explanation. The Committee discussed the draft product information and noted two peer review reports.

- 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 chickens (EMEA/V/C/003829/0000). The Committee agreed that an oral explanation will not be necessary. The Committee discussed the draft product information, and noted two peer review reports and the comments received from CVMP members.

- The Committee adopted the updated scientific overview and benefit-risk assessment including the list of outstanding issues for a marketing authorisation application for a new viral vaccine for pigs (EMEA/V/C/003942/0000). The Committee agreed that an oral explanation will not be necessary. 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

- The Committee adopted the scientific overview and benefit-risk assessment including the list of questions and agreed comments on the draft product information for an extension application for **Poulvac E. coli** (EMEA/V/C/002007/X/0008), to include a new target species. The Committee noted a peer review report and the comments received from CVMP members.

2.4 Re-examination of CVMP opinions

- The Committee adopted by consensus (29 members present of those eligible to vote) the final CVMP opinion and the final CVMP assessment report for **Lodipressin** (EMEA/V/C/003786/0000), recommending the refusal of the granting of a marketing authorisation. Lodipressin had a proposed indication for cardiovascular use in cats. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP.

2.5 Other issues

- The Committee agreed to the request from the applicant for an extension to the clock-stop for an extension application for **ZACTRAN** (EMEA/V/C/000129/X/0027), to include a new target species.
- The Committee agreed to the request from the applicant for an extension to the clock-stop for an extension application for **DRAXXIN** (EMEA/V/C/000077/X/0029), to include a new target species for the solution for injection range.
- The Committee endorsed the EPAR module 6 scientific discussion for **Rheumocam** (EMEA/V/C/000121/X/0015) concerning the extension of the 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 type II variation for **Nobivac L4** (EMEA/V/C/002010/II/0003), recommending the variation of the marketing authorisation to include a mixed use claim. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP.

3.2 Oral explanations and lists of outstanding issues

- There were no items for discussion.

3.3 Lists of questions

- The Committee adopted the list of questions for a quality type II variation for **RESPIPORC FLU3** (EMEA/V/C/000153/II/0010).
- The Committee adopted the list of questions for a quality type II variation for **Gripovac 3** (EMEA/V/C/000157/II/0018).

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 adopted by majority (23 members in favour out of the 31 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for the referral procedure for **Gutal 1000 g/kg premix for medicated feeding stuff for pigs** (EMEA/V/A/108), concluding that the objections raised by France and the Netherlands during the decentralised procedure should not prevent the granting of a marketing authorisation, subject to changes in the product information recommending risk mitigation measures.
  Z. Auce, F. Klein, B. Kolar, J.-C. Rouby, J. Schefferlie, M. Schmit, S. Srčič, B. Zemann, and the

Icelandic and Norwegian CVMP members signed a divergent position not supporting the aforementioned recommendation.

- The Committee heard an oral explanation from the marketing authorisation holder, CEVA-Phylaxia Veterinary Biologicals Co. Ltd., and discussed the updated rapporteur's assessment report and the updated co-rapporteur's assessment report for the referral procedure for **Coglapix vakcina A.U.V. suspension for injection for pigs** (EMEA/V/A/109). The adoption of the opinion is foreseen for the June 2015 meeting of the Committee.

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 considered the notification from Belgium for a referral procedure for **all veterinary medicinal products containing a combination of lincomycin and spectinomycin to be administered orally to pigs and/or poultry**, concerning the indications, dosage and withdrawal periods of the products. The Committee agreed to start a referral procedure (EMEA/V/A/110) under Article 35 and appointed B. Urbain as rapporteur and K. Baptiste as co-rapporteur. The Committee adopted the list of questions and the timetable, and noted the list of products concerned.
- The Committee considered the notification from the European Commission for a referral procedure for **all veterinary medicinal products containing colistin in combination with other antimicrobial substances to be administered orally**, concerning antimicrobial resistance. The Committee agreed to start a referral procedure (EMEA/V/A/111) under Article 35 and appointed K. Baptiste as rapporteur and M. Holzhauser-Alberti as co-rapporteur. The Committee adopted the list of questions and the timetable, and noted the list of products concerned.

4.4 Article 78 of Directive 2001/82/EC

- There were no items for discussion.

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

- There were no items for discussion.

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

- There were no items for discussion.

4.7 Other issues

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.

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 **Nobivac Myxo RHD** (EMEA/V/C/002004/REC/011).

5.3 Product anniversary list

- The Committee endorsed the product anniversary list for the period between 11/04/2015 – 07/05/2015:

Product	Period
BLUEVAC BTV8 (EMEA/V/C/000156)	14/04/2014 – 13/04/2015
CERTIFECT (EMEA/V/C/002002)	06/05/2014 – 05/05/2015
Equilis StrepE (EMEA/V/C/000078)	07/05/2014 – 06/05/2015
Meloxidolor (EMEA/V/C/002590)	22/04/2014 – 21/04/2015
Neocolipor (EMEA/V/C/000035)	14/04/2014 – 13/04/2015
Oncept IL-2 (EMEA/V/C/002562)	03/05/2014 – 02/05/2015
Parvoduk (EMEA/V/C/002740)	11/04/2014 – 10/04/2015
Procox (EMEA/V/C/002006)	20/04/2014 – 19/04/2015
Purevax FeLV (EMEA/V/C/000056)	13/04/2014 – 12/04/2015
Veraflox (EMEA/V/C/000159)	12/04/2014 – 11/04/2015
Versican Plus DHPPi/L4 (EMEA/V/C/003678)	07/05/2014 – 06/05/2015
Versican Plus DHPPi/L4R (EMEA/V/C/002759)	07/05/2014 – 06/05/2015
Zuprevo (EMEA/V/C/002009)	06/05/2014 – 05/05/2015

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 **RHINISENG** (EMEA/V/C/000160/R/0003), 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 discussed the request from the MAH, CEVA Sante Animale for the re-examination of the CVMP opinion adopted on 10 April 2015 on the renewal of **COXEVAC** (EMEA/V/C/000155/R/0009), and appointed E. Werner as rapporteur for the procedure. The adoption of the final CVMP opinion is foreseen for the June 2015 meeting of CVMP.

5.5 Pharmacovigilance – PSURs and SARs

- The Committee noted receipt of the final study report for the post-authorisation safety study for **Parvoduk,** which was presented by the rapporteur.

- 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
Broadline (EMEA/V/C/002700)	01.07.2014 – 31.12.2014
BTVPUR AlSap 1 (EMEA/V/C/002230)	01.07.2014 – 31.12.2014
BTVPUR AlSap 1-8 (EMEA/V/C/002231)	01.07.2014 – 31.12.2014
Cardalis (EMEA/V/C/002524)	01.08.2014 – 31.01.2015
Cerenia (EMEA/V/C/000106)	01.07.2014 – 31.12.2014
Circovac (EMEA/V/C/000114)	01.01.2014 – 31.12.2014
Contacera (EMEA/V/C/002612)	01.07.2014 – 31.12.2014
Equilis Prequenza (EMEA/V/C/000094)	01.08.2014 – 31.01.2015
Equilis Prequenza Te (EMEA/V/C/000095)	01.08.2014 – 31.01.2015
ERYSENG (EMEA/V/C/002761)	04.07.2013 – 31.01.2015
ERYSENG PARVO (EMEA/V/C/002762)	04.07.2013 – 31.01.2015
Melosus (EMEA/V/C/002001)	01.03.2014 – 28.02.2015
Poulvac E.coli (EMEA/V/C/002007)	01.07.2014 – 31.12.2014
Slentrol (EMEA/V/C/000116)	01.06.2014 – 30.11.2014
Trifexis (EMEA/V/C/002635)	05.07.2015 – 04.01.2015
TruScient (EMEA/V/C/002000)	01.06.2014 – 30.11.2014
Vectra 3D (EMEA/V/C/002555)	01.07.2014 – 31.12.2014

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

5.6 Supervisions and sanctions

Information relating to supervisions and sanctions will not be published as it would be undermining the purpose of such inspections.

The following document was circulated for information:

- Status report on PSURs for centrally authorised veterinary medicinal products.

6. CO-OPERATION WITH OTHER EU OR INTERNATIONAL BODIES

6.1 VICH

- The Committee endorsed the revised draft VICH guideline 52 on bioequivalence: blood level bioequivalence study and the annex with the final EU comments for sign-off by the EWG at step 5 of the VICH process. It was noted that the current CVMP bioequivalence guideline will not fully be replaced by the new VICH guideline, as it is covering a wider area of topics, but the CVMP guideline will need to be revised once the VICH one is finalised to remove redundant aspects.

- The Committee endorsed draft 4 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 on draft 3, for circulation to the VICH EWG by the topic leader (step 2 of the VICH process).

6.2 Codex Alimentarius

- The Committee received a verbal report from EMA on the 22nd session of the Codex Committee on residues of veterinary drugs in foods (CCRVDF) held on 27 April – 1 May 2015 in San Jose, Costa Rica, and noted the agenda of the meeting.

6.3 Other EU bodies and international organisations

- The Committee nominated G. Hahn as the expert representing CVMP for a new EFSA working group on *Echinococcus multilocularis*.
- The Committee nominated B. Kolar as CVMP representative to attend the ECHA/EFSA topical scientific workshop on soil risk assessment, to be held on 7-8 October 2015 in Helsinki, Finland.
- The Committee nominated E. Lander Persson and J. Schefferlie as CVMP representatives to attend the EFSA's second scientific conference 'Shaping the future of food safety, together' to be held on 14-16 October 2015 in Milan, Italy.
- The Committee received a verbal report from N. Joseph and discussed the draft EFSA opinion on reference points for action for nitrofurans.

The following document was circulated for information:

- Status of active VICH guidelines and action plan of CVMP and working parties.

7. WORKING PARTIES AND SCIENTIFIC ADVISORY GROUPS

Information relating to certain topics discussed under section 7 at this meeting cannot be released at the present time as it is deemed to be confidential.

7.1 Scientific Advice Working Party (SAWP-V)

Information relating to SAWP-V procedures cannot be released at the present time as it is deemed to be commercially confidential.

- The Committee received a verbal report from the chair of the SAWP-V on the meeting held on 5 May 2015, and noted the agenda of the meeting.

7.2 Quality Working Party (QWP)

7.3 Safety Working Party (SWP-V)

- There were no items for discussion.

7.4 Environmental Risk Assessment Working Party (ERAWP)

7.5 Efficacy Working Party (EWP-V)

- There were no items for discussion.

7.6 Antimicrobials Working Party (AWP)

7.7 Immunologicals Working Party (IWP)

7.8 Pharmacovigilance Working Party (PhVWP-V)

- There were no items for discussion.

7.9 Novel therapy groups and related issues

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 following documents were circulated for information:

- Minutes of the SAWP-V meeting held on 8 April 2015;
- Draft agenda of the 75th QWP Joint CHMP/CVMP QWP meeting to be held on 26-28 May 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.

- 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.28), which was updated to include diethylhexyladipate under the heading of excipients following the conclusion of a scientific advice procedure on this topic.

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 discussed the CVMP Strategy on Antimicrobials 2016 to 2020 and appointed members to prepare a first draft of the CVMP strategy.
- The Committee discussed the report from the virtual meeting between EFSA, EMA and EC held on 15 April 2015, concerning the request from European Commission for a joint EFSA and EMA scientific opinion on measures to reduce the need to use antimicrobial agents in animal husbandry in the EU.

8.4 Pharmacovigilance

- There were no items for discussion.

8.5 Other issues

Information on other critical issues related to centralised procedures cannot be released at the present time as it is deemed to contain commercially confidential information.

- There were no items for discussion.

9. AVAILABILITY OF MEDICINES AND MUMS CLASSIFICATION

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

10. PROCEDURAL AND REGULATORY MATTERS

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

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

10.2 Regulatory matters

Information relating to certain regulatory issues cannot be released at the present time as it is deemed to be commercially confidential.

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

- The Committee discussed the CMDv position paper on in-use shelf-life of tablet fractions.
- The Committee received a verbal report from the chair of CMDv on the meeting held on 9-10 April 2015, and noted the draft minutes of the meeting, as well as the draft agenda of the meeting held on 7-8 May 2015.

12. ORGANISATIONAL AND STRATEGIC MATTERS

- The Committee adopted the agenda of the CVMP Interested Parties' meeting to be held on 6 May 2015.
- The Committee noted the draft EU Medicines Agencies Network Strategy to 2020. The deadline for submitting comments is 30 June 2015.
- The Committee discussed the document prepared by the chair on the cooperation and exchanges between CVMP and CMDv, which was in principle supported.
- The Committee was informed of the financial incentives for vaccines against certain epizootic diseases.
- The Committee was informed that the data gathering exercise by the Management Board to collect high quality evidence needed by the European Commission in drafting the future legislative proposals on fees related to the activities of the EMA has been extended to include veterinary procedures.
- The Committee was informed of the planned events to bring together staff, experts and Committee members for debates on different areas of their work under the EMA 20th anniversary programme. A session on a veterinary topic related to innovative veterinary medicines and global food security is planned for the evening (Wednesday, 7 October 2015) during the October CVMP meeting.

- The Committee noted the table of actions following the April 2015 CVMP meeting.

13. LEGISLATION

- There were no items for discussion.

14. ANY OTHER BUSINESS

- Upon the completion of the May 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 May 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	Full involvement	
BG	Emil Kozhuharov	Full involvement	
CY	Alia Michaelidou	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	
FI	Martti Nevalainen	Full involvement	
HR	Ljiljana Markuš-Cizelj	No part in discussions, final deliberations and voting as appropriate, and cannot act as rapporteur for:	• 2.1 Innovax-ILT (EMEA/V/C/003869) • 2.1 Canigen L4 (EMEA/V/C/004079) • 2.2 EMEA/V/C/002763 • 2.2 EMEA/V/C/003942 • 3.1 Nobivac L4 (EMEA/V/C/002010/II/0003) • 5.2 Nobivac Myxo-RHD • 5.5 Equilis Prequenza, Equilis Prequenza Te
HU	Gábor Kulcsár	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	
SE	Eva Lander Persson	Full involvement	
SI	Stane Srčič	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	

Country	CVMP Member	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
IS	Jóhann Lenharðsson	Full involvement	
NO	Hanne Bergendahl	Full involvement	

Country	CVMP Alternate	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
BE	Frédéric Klein	Full involvement	
DE	Esther Werner	Full involvement	
DK	Merete Blixenkrone-Møller	Full involvement	
ES	Consuelo Rubio Montejano	Full involvement	
FR	Jean-Claude Rouby	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.			
BE	Sandy Vermout *(remotely)*	Full involvement	
FR	Michael Holzhauser-Alberti *(remotely)*	Full involvement	
FR	Sylvie Louet	Full involvement	
NL	Jaqueline Poot *(remotely)*	Full involvement	
SE	Henrik Wahlstrom *(remotely)*	Full involvement	
UK	Noel Joseph	Full involvement	
UK	Niall O'Brien	Full involvement	
UK	Javier Pozo	Full involvement	
UK	Stephen Spencer *(remotely)*	Full involvement	
UK	Kenneth Stapleton	Full involvement	

CVMP working parties and CMDv	Chair
AWP	Helen Jukes
CMDv	--
ERAWP	Boris Kolar
EWP-V	Gesine Hahn

CVMP working parties and CMDv	Chair
IWP	Esther Werner
PhVWP-V	--
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