3 June 2014
EMA/CVMP/337845/2014
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Minutes of the 6-8 May 2014 meeting

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

Note on access to documents

Some documents mentioned in the 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).

1. Adoption of the Agenda

The Committee adopted the agenda with no modifications.

2. CVMP delegates' list of intended participation and identified conflicts of interests with regards to agenda items

The attendance list was completed and conflicts of interests were identified for the May 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 18 members were needed for an absolute majority.

3. 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 present time as it is deemed to be commercially confidential.

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4. Adoption of the minutes of the previous meeting

The minutes of the April 2014 meeting were adopted with no amendments.

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

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

A. ADOPTION OF OPINIONS/LIST OF QUESTIONS

A.1 ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS

A.1.1 Opinions on applications

- The Committee adopted by consensus (27 members present of those eligible to vote) the CVMP opinion, including the EPMAR and the CVMP assessment report, for the establishment of MRLs in Equidae for **clodronic acid (in the form of disodium salt)** (EMEA/V/MRL/002860/FULL/0002). The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP. The Committee noted the report from EU-RL, two peer review reports and the comments received from CVMP members.

A.1.2 Recommendations for extrapolation of established MRLs

- There were no items for discussion.

A.1.3 Re-examination of CVMP opinions

- There were no items for discussion.

A.2 COMMUNITY MARKETING AUTHORISATIONS

A.2.1 Opinions on applications

- 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 **Versican Plus Pi** (EMEA/V/C/003681/0000), recommending the granting of a marketing authorisation. The product is a new viral vaccine containing live parainfluenza virus for dogs. 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 **Versican Plus DHPPi** (EMEA/V/C/003679/0000), recommending the granting of a marketing authorisation. The product is a new viral vaccine containing live canine distemper virus, live canine adenovirus, live parainfluenza virus and live canine parvovirus for dogs. 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 **ERYSENG PARVO** (EMEA/V/C/002762/0000), recommending the granting of a marketing authorisation. The product is a new bivalent viral and bacterial vaccine containing inactivated *Erysipelothrix rhusiopathiae* and inactivated porcine parvovirus for pigs. 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 **ERYSENG** (EMEA/V/C/002761/0000), recommending the granting of a marketing authorisation. The product is a new bacterial vaccine containing inactivated *Erysipelothrix rhusiopathiae* for pigs. 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 **DRAXXIN** (EMEA/V/C/000077/X/0026), recommending the extension of the marketing authorisation to add a new strength: 25 mg/ml solution for injection for pigs. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP. The Committee noted the summary of opinion for publication.

A.2.2 Variations to Community marketing authorisations

- The Committee received an oral explanation from Bayer Animal Health, concerning a type II variation for **Profender** (EMEA/V/C/000097/II/0024), to change the legal status of Profender spot-on solution for cats from prescription to non-prescription. The Committee noted the rapporteurs' assessment report.
- The Committee adopted by consensus (29 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for a type II variation for **Cerenia** (EMEA/V/C/000106/II/0022), recommending the variation of the marketing authorisation to extend the use of Cerenia tablets from 5 to 14 consecutive days. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted by consensus (26 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for a grouped type II quality variation for **Metacam** (EMEA/V/C/000033/II/0108/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 (26 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for a worksharing type IB variation for **Vectra 3D** (EMEA/V/C/002555/WS/0532 (002)), recommending the variation of the marketing authorisation to change the existing pharmacovigilance system described in the Detailed Discription of the Pharmacovigilance System (DDPS), including the change of the Qualified Person for Pharmacovigilance (QPPV). The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted the CVMP list of questions for a type II quality variation for **STARTVAC** (EMEA/V/C/000130/II/0002).
- The Committee adopted the CVMP list of questions for a worksharing type II quality variation for **Fevaxyn Pentofel** (EMEA/V/C/000030/WS/0489/G (039)).
- The Committee adopted the CVMP list of outstanding issues for a type II variation for **ProteqFlu** (EMEA/V/C/000073/II/0014) to substitute a strain.
- The Committee adopted the CVMP list of outstanding issues for a type II variation for **ProteqFlu-Te** (EMEA/V/C/000074/II/0017) to substitute a strain.

- The Committee adopted the CVMP list of questions for a grouped type quality II variation for **Equip WNV** (EMEA/V/C/000137/II/0018/G).
- The Committee adopted the CVMP list of questions for a type II variation for **AFTOVAXPUR DOE** (EMEA/V/C/002292/II/0002).

A.2.3 Re-examination of CVMP opinions

- There were no items for discussion.

A.2.4 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 **Metacam** (EMEA/V/C/000033/X/0107), to include a new strength for cattle and horses. The Committee noted a peer review report.

A.3 REFERRALS AND RELATED PROCEDURES

A.3.1 Article 33 of Directive 2001/82/EC

- There were no items for discussion.

A.3.2 Article 34 of Directive 2001/82/EC

- There were no items for discussion.

A.3.3 Article 35 of Directive 2001/82/EC

- The Committee considered a request for a clock stop to provide additional data related to the outstanding issues for the referral procedure for **Suanovil 20 and associated names, Captalin and associated names and generic products thereof, including pending applications** (EMEA/V/A/086) concerning the indications, dosage and withdrawal periods. The Committee agreed on a one month clock stop and endorsed the revised timetable. The Committee discussed the rapporteur's assessment on the responses to the list of outstanding issues and the revised rapporteurs' joint assessment report. The adoption of the CVMP opinion and assessment report is foreseen for the July 2014 meeting of the Committee.
- The Committee adopted by consensus (29 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for the referral procedure for **veterinary medicinal products containing tylosin to be administered orally via feed or the drinking water to pigs** (EMEA/V/A/100), recommending changes to the product information of the concerned products related to deletion of the indication for swine dysentery (caused by *Brachyspira hyodysenteriae*) and limiting the treatment durations for up to three weeks in pigs. The Icelandic and Norwegian CVMP members agreed with the above-mentioned recommendation of the CVMP.

A.3.4 Article 39 of Directive 2001/82/EC

- There were no items for discussion.

A.3.5 Article 13 of Regulation (EC) No 1234/2008

- There were no items for discussion.

A.3.6 Article 78 of Directive 2001/82/EC

- There were no items for discussion.

A.3.7 Article 30(3) of Regulation 726/2004

- The Committee discussed a question forwarded by EDQM regarding the Article 30(3) procedure for **dapsone** (EMEA/V/A/075).
- The Committee discussed the revised rapporteur's assessment report including the co-rapporteur's critique for the Article 30(3) procedure for **lidocaine** (EMEA/V/A/092). The Committee noted three peer review reports and the comments received from CVMP members.

A.3.8 Article 45 of Regulation 726/2004

- There were no items for discussion.

A.3.9 Miscellaneous items

Information relating to some referral procedures cannot be released at this meeting as it is deemed to be confidential.

B. MARKETING AUTHORISATION APPLICATIONS FOR DISCUSSION AND DECISION

- The Committee adopted the updated scientific overview and benefit-risk assessment including the list of outstanding issues for a marketing authorisation application for a new product (EMEA/V/C/003684/0000), a vaccine for dogs. The Committee discussed the draft product information and noted two peer review reports and the comments received from CVMP members, and agreed to invite the applicant for an oral explanation in September 2014.
- The Committee discussed the joint rapporteurs' assessment of the responses to the list of outstanding issues and the draft product information for a marketing authorisation application for a new otological product (EMEA/V/C/003753/0000) for dogs. The adoption of the CVMP opinion and assessment report is foreseen for the June 2014 meeting of the Committee.
- The Committee agreed to extend the clock-stop for a marketing authorisation application for a new product (EMEA/V/C/002390/0000), a vaccine for Atlantic salmon, following a request from the applicant.

C. POST-AUTHORISATION ISSUES (EXCLUDING VARIATIONS)

C.1 General issues

- There were no items for discussion.

C.2 Post-authorisation measures to CVMP opinions on the granting of Community marketing authorisations and annual reassessments

- The Committee adopted the rapporteur's recommendation assessment report for **CERTIFECT** (EMEA/V/C/002002).
- The Committee adopted the rapporteur's recommendation assessment report for **Porcilis ColiClos** (EMEA/V/C/002011).

C.3 Product anniversary list

- The Committee noted the product anniversary list for the period between 11.04.2014 – 08.05.2014:

Product	Period
BLUEVAC BTV8 (EMEA/V/C/000156)	14.04.2013 – 13.04.2014
CERTIFECT (EMEA/V/C/002002)	06.05.2013 – 05.05.2014
Equilis StrepE (EMEA/V/C/000078)	07.05.2013 – 06.05.2014
Meloxidolor (EMEA/V/C/002590)	22.04.2013 – 21.04.2014
Neocolipor (EMEA/V/C/000035)	14.04.2013 – 13.04.2014
Oncept IL-2 (EMEA/V/C/002562)	03.05.2013 – 02.05.2014
Procox (EMEA/V/C/002006)	20.04.2013 – 19.04.2014
Purevax FeLV (EMEA/V/C/000056)	13.04.2013 – 12.04.2014
Slentrol (EMEA/V/C/000116)	13.04.2013 – 12.04.2014
Veraflox (EMEA/V/C/000159)	12.04.2013 – 11.04.2014
Zuprevo (EMEA/V/C/002009)	06.05.2013 – 05.05.2014

C.4 Renewals of marketing authorisations

- There were no items for discussion.

C.5 Pharmacovigilance – PSURs and SARs

- The Committee discussed the CVMP PSUR assessment report for **DRAXXIN** (EMEA/V/C/000077) for the period 01.12.2010-30.11.2013 and the comments received. The Committee agreed that additional information should be requested from the MAH before the assessment of the PSUR could be concluded.
- The Committee endorsed the list of products and calendar for signal detection analysis.
- 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
BTVPUR AlSap 1 (EMEA/V/C/002230)	01.07.2013-31.12.2013
BTVPUR AlSap 1-8 (EMEA/V/C/002231)	01.07.2013-31.12.2013
Cardalis (EMEA/V/C/002524)	01.08.2013-31.01.2014
Cerenia (EMEA/V/C/000106)	01.07.2013-31.12.2013
Circovac (EMEA/V/C/000114)	01.01.2013-31.12.2013
Contacera (EMEA/V/C/002612)	01.07.2013-31.12.2013
Convenia (EMEA/V/C/000098)	01.01.2011-31.12.2013
Ibaflin (WD) (EMEA/V/C/000052)	01.01.2011-31.12.2013
Inflacam (EMEA/V/C/000093)	01.07.2013-31.12.2013
Masivet (EMEA/V/C/000128)	01.12.2013-30.11.2013

Panacur AquaSol (EMEA/V/C/002008)	01.07.2013-31.12.2013
Poulvac E. coli (EMEA/V/C/002007)	01.07.2013-31.12.2013
Suvaxyn Aujeszky 783+O/W (EMEA/V/C/000038)	01.01.2011-31.12.2013

C.6 Supervisions and sanctions

- There were no items for discussion.

The following document was circulated for information:

- Status report on periodic safety update reports (PSURs) for centrally authorised veterinary medicinal products.

D. CO-OPERATION WITH OTHER EU OR INTERNATIONAL BODIES

D.1 VICH

- The Committee reviewed draft 8 of 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) and confirmed that it was satisfied with the document.
- The Committee reviewed draft 2 of the VICH metabolism and residue kinetics guideline on residue studies in fish in preparation for the VICH EWG meeting to be held in June 2014. The Committee noted the comments received from CVMP and SWP members and agreed that its expert would compile the final EU comments based on the CVMP conclusions for submission to the EWG.
- The Committee endorsed the principles for the completion of the responses to the questionnaire to collect information on combination products in regions for the VICH Task Force on Efficacy Studies for Combination Products (TFcomb) to be finalised by the secretariat and the EU expert.
- The Committee noted the EU comments on the revised draft summary of discussion and the proposal for action plan for the draft concept paper for the revision of VICH Stability GL 3(R) to include climatic zones III and IV, which had been agreed by written procedure consulting QWP and CVMP.

D.2 Codex Alimentarius

- There were no items for discussion.

D.3 Other EU bodies and international organisations

- The Committee endorsed the request from the HMA for the Agency to organise a Focus Group meeting involving CVMP and its Immunologicals working party on the requirements for the authorisation of vaccines in the EU. Further discussions will be held with HMA and with stakeholders to define an agenda for the event and CVMP will be informed on progress.

The following document was circulated for information:

- Status of VICH guidelines and meeting schedule of the VICH Expert Working Groups.

E. WORKING PARTIES AND SCIENTIFIC ADVISORY GROUPS

E.1 Scientific Advice Working Party (SAWP)

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

- The Committee received a verbal report from the vice-chair of the SAWP on the meeting held on 6 May 2014, and noted the agenda of the meeting.

E.2 Pharmacovigilance Working Party (PhVWP)

- The Committee received a verbal report from the chair of the PhVWP on the meeting held on 25-26 March 2014, and noted the agenda and draft minutes of the meeting.

E.3 Efficacy Working Party (EWP)

- The Committee adopted the question and answer document related to the CVMP Guideline on pharmaceutical fixed combination products extending the existing question and answer document regarding a justification of a fixed combination, and adding a new question and answer concerning the ease of administration as justification for fixed combination products.

E.4 Safety Working Party (SWP)

- There were no items for discussion.

E.5 Immunologicals Working Party (IWP)

- There were no items for discussion.

E.6 Quality Working Party (QWP)

- The Committee adopted the reflection paper on the use of cocrystals and other solid state form of active substances in medicinal products.

E.7 Environmental Risk Assessment Working Party (ERAWP)

- The Committee discussed the further approach on the finalisation and implementation of the draft CVMP guideline on the assessment of persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) substances in veterinary medicinal products. It is planned that the PBT guideline will be adopted at the October 2014 meeting of the Committee.

E.8 Antimicrobials Working Party (AWP)

Information relating to AWP topics discussed at this meeting cannot be released at present time as it is deemed to be confidential.

E.9 Joint CVMP/CHMP AHEG on the application of the 3Rs (JEG 3Rs)

- There were no items for discussion.

E.10 Other working party issues

- There were no items for discussion.

The following documents were circulated for information:

- Minutes of the Scientific Advice Working Party meeting held on 8 April 2014.
- Draft agenda of the EWP-v meeting to be held on 13-14 May 2014.

- Draft agenda of the 71st joint CHMP/CVMP QWP meeting to be held on 13-15 May 2014.
- Draft agenda of the AWP meeting to be held on 14-15 May 2014.

F. SAFETY OF VETERINARY MEDICINES AND RESIDUES

F.1 Appointment of rapporteurs, co-rapporteurs and peer reviewers for the establishment of new MRLs

Information relating to notifications of intent for new MRL applications cannot be released at present time as it is deemed to be commercially confidential.

- The Committee discussed the request from the Commission for the review of the previous MRL opinion on diflubenzuron in Salmonidae under Article 11 of Regulation (EC) No 470/2009 (EMA/V/MRL/003135/MODF/0003) in view of recent evaluations by ECHA and EFSA in the context of biocides and plant protection products, and concerns relating to the genotoxic potential of the metabolite 4-chloroaniline.

F.2 Critical issues related to centralised procedures

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

- There were no items for discussion.

F.3 Other MRL items

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

- The Committee considered the request for the inclusion of **bentonite** in the list of substances considered as not falling within the scope of Regulation (EC) No 470/2009 (EMA/CVMP/206726/2014), and agreed to its inclusion as an excipient in the list.
- 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.20).

F.4 Antimicrobial resistance

- The Committee discussed the statement of the Danish Council of Ethics on the use of antibiotics and agreed that there was no need for a presentation at CVMP on the topic due to time constrains. The CVMP applauded the initiative of the Danish Council of Ethics and agreed that a thank you letter would be sent to them.

F.5 Pharmacovigilance

- There were no items for discussion.

G. APPLICATIONS FOR GRANTING OF COMMUNITY MARKETING AUTHORISATIONS

G.1 Eligibility and appointment of rapporteurs, co-rapporteurs and peer reviewers

Information concerning notifications of intent and eligibility requests relating to community marketing authorisations cannot be released at present time as it is deemed to be commercially confidential.

- The Committee agreed to the transfer of co-rapporteur and peer reviewer responsibilities from H. Østensen to T. Høy.

G.2 Inspections

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

G.3 Regulatory issues

Information relating to certain regulatory issues on community marketing authorisations cannot be released at present time as it is deemed to be commercially confidential.

G.4 Miscellaneous items

Information relating to certain miscellaneous items on community marketing authorisations cannot be released at present time as it is deemed to be commercially confidential.

- The Committee endorsed the EPAR module 6 scientific discussion for **Vectra Felis** (EMEA/V/C/002746/0000).
- The Committee noted the withdrawal letter from Dechra Veterinary Products A/S for **Flexicam**.

H. 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.

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

- The Committee noted the draft minutes of the meeting held on 10-11 April 2014 and the draft agenda of the meeting held on 7-8 May 2014.

J. ORGANISATIONAL MATTERS

- The Committee discussed the draft agenda of the CVMP Interested Parties' meeting, held on 7 May 2014 at the EMA, and noted the draft minutes of the previous meeting held on 15 May 2013.
- The Committee endorsed the recommendations for the organisation and running of rapporteurs' meetings via Adobe Connect which are aimed to support the efficient conduct of virtual rapporteurs' meetings.
- The Committee was informed about the planned presidency CVMP and Joint CVMP/CMDv meetings to be held in September 2014 in Rome, Italy.
- The Committee received a presentation on the upcoming move of the Agency.
- The Committee noted a letter from the EMA Executive Director to delegates on the move to 30 Churchill Place.

K. LEGISLATION

- There were no items for discussion.

L. ANY OTHER BUSINESS

- The draft press release was circulated for members to provide any comments.

ANNEX I - List of participants including any restrictions with respect to involvement of members / alternates / experts following evaluation of declared interests for the May 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**	
BE	Bruno Urbain	Full involvement	
BG	Damyan Iliev	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	Irmeli Happonen	Full involvement	
FR	Michael Holzhauser-Alberti	Full involvement	
HR	Ljiljana Markuš-Cizelj	No part in discussions, final deliberations and voting as appropriate, and cannot act as rapporteur for:	• C.2 Porcilis Coliclos • C.5 Equilis Te, Ibaflin, Panacur AquaSol
HU	Gábor Kulcsár	Full involvement	
IE	David Murphy (vice-chair)	Full involvement	
LV	Zanda Auce	Full involvement	
MT	Stephen Spiteri	Full involvement	
PL	Ewa Augustynowicz	Full involvement	
PT	João Duarte Da Silva	Full involvement	
RO	Lollita Taban	Full involvement	
SE	Eva Lander Persson	Full involvement	
SI	Stane Srčič	Full involvement	
SK	Judita Hederova	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
AT	Ines Lindner	Full involvement	
BE	Frédéric Klein	Full involvement	
DE	Esther Werner	Full involvement	
DK	Merete Blixenkrone-	Full involvement	

Country	CVMP Alternate	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
	Møller		
ES	Consuelo Rubio Montejano	Full involvement	
FR	Jean-Claude Rouby	Full involvement	
NL	Peter Hekman	Full involvement	
NO	Tonje Høy	Full involvement	
PL	Anna Wachnik-Święcicka	Full involvement	
SE	Frida Hasslung Wikström	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.			
UK	Katharine Healey *(remotely)*	Full involvement	
UK	Rory Cooney *(remotely)*	Full involvement	
UK	Stephen Spencer *(remotely)*	Full involvement	
UK	Noel Joseph *(remotely)*	Full involvement	

CVMP working parties and CMDv	Chair
AWP	Helen Jukes
ERAWP	Boris Kolar
EWP	Gesine Hahn
IWP and CMDv	Esther Werner
PhVWP	Peter Ekström *(remotely)*
SAWP	Rory Breathnach

Observers	
Johan Schefferlie	

Observer from the European Commission	
Present	

European Medicines Agency support
The meeting run with relevant support from the EMA staff