8 September 2015
EMA/CVMP/600373/2015
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Minutes of the 7-9 July 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 July 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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iv. Adoption of the minutes of the previous meeting

The minutes of the June 2015 meeting were adopted with a minor amendment.

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 rapporteurs' joint assessment of the responses to the list of questions for the establishment of MRLs in caprine species, *Equidae*, fin fish and rabbits for a substance (EMEA/V/MRL/004047/FULL/0001). The Committee adopted a list of outstanding issues to be addressed in writing. An oral explanation would be convened if the applicant would request to address the outstanding issues with the Committee. The Committee noted the rapporteur's draft EPMAR, two peer review reports and the comments received from CVMP members. The adoption of the opinion is foreseen for the November 2015 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 majority (24 members in favour out of the 28 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **FORTEKOR PLUS** (EMEA/V/C/002804/0000), recommending the granting of a marketing authorisation. FORTEKOR PLUS is a new cardiovascular product containing a combination of pimobendan and benazepril hydrochloride in tablets for oral use for the treatment of congestive heart failure in dogs. The Icelandic CVMP member agreed with the above-mentioned recommendation of the CVMP. K. Baptiste, E. Lander Persson, J.-C. Rouby and G. J. Schefferlie signed a divergent position not supporting the aforementioned recommendation. The Committee noted the summary of opinion for publication.
- The Committee adopted by consensus (26 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **PORCILIS PCV ID** (EMEA/V/C/003942/0000), recommending the granting of a marketing authorisation. The

product is a new viral vaccine against PCV2 infection in pigs. The Icelandic CVMP member agreed with the above-mentioned recommendation of the CVMP. The Committee noted the summary of opinion for publication.

- 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 **Vectormune ND** (EMEA/V/C/003829/0000), recommending the granting of a marketing authorisation. The product is a new live viral vaccine against Newcastle disease and Marek's disease in chickens. The Icelandic CVMP member agreed with the above-mentioned recommendation of the CVMP. The Committee noted the summary of opinion for publication.

- 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 **Novaquin** (EMEA/V/C/003866/0000), recommending the granting of a marketing authorisation. The product is a new anti-inflammatory oral suspension containing meloxicam for the alleviation of inflammation and relief of pain in musculo-skeletal disorders in horses. 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 adopted the scientific overview and benefit-risk assessment including the list of outstanding issues for a marketing authorisation application for a new ectoparasiticide for dogs (EMEA/V/C/003991/0000). The Committee agreed that an oral explanation would not be necessary. The Committee discussed the draft product information, and 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 outstanding issues for a marketing authorisation application for a new corticosteroid product for dogs (EMEA/V/C/003782/0000). The Committee agreed that an oral explanation would not be necessary. The Committee discussed the draft product information, and noted a peer review report.

- The Committee adopted the scientific overview and benefit-risk assessment including the list of outstanding issues for a marketing authorisation application for a new viral and bacterial vaccine for pigs (EMEA/V/C/003924/0000). The Committee agreed that an oral explanation would not be necessary. The Committee discussed the draft product information, and noted two peer review reports 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 **Inflacam** (EMEA/V/C/002497/X/0009), to add a new strength and a new pharmaceutical form for horses.

2.4 Re-examination of CVMP opinions

- There were no items for discussion.

2.5 Other issues

- The Committee endorsed the EPAR module 6 scientific discussion for **Innovax-ILT** (EMEA/V/C/003869/0000), concerning the granting of the initial marketing authorisation.

- The Committee endorsed the EPAR module 6 scientific discussion for **Lodipressin** (EMEA/V/C/003786/0000), concerning the refusal of the granting of the initial marketing authorisation.
- The Committee endorsed the EPAR module 6 scientific discussion for **UpCard** (EMEA/V/C/003836/0000), concerning the granting of the initial marketing authorisation.
- The Committee endorsed the EPAR module 6 scientific discussion for **Canigen L4** (EMEA/V/C/004079/0000), concerning the granting of the initial marketing authorisation.

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

- 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 a quality type II variation for **Hiprabovis IBR Marker Live** (EMEA/V/C/000158/II/0006), 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 (29 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for a grouped type II variation for **Advocate** (EMEA/V/C/000076/II/0026/G), recommending the variation of the marketing authorisation to add a new indication for dogs for the treatment of cutaneous dirofilariosis, and a change to the local representatives. The Icelandic CVMP member agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted by consensus (29 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for a quality type II variation for **Suvaxyn CSF Marker** (EMEA/V/C/002757/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 (29 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for a quality worksharing type IB variation for **Purevax RCPCh** and **Purevax RCPCh FeLV** (EMEA/V/C/xxxxxx/WS/0759), recommending the variation of the marketing authorisations. The Icelandic CVMP member agreed with the above-mentioned recommendation of the CVMP.
- 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 a quality type II variation for **Oxyglobin** (EMEA/V/C/000045/II/0021), 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 (29 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for a type II variation for **Ingelvac CircoFLEX** (EMEA/V/C/000126/II/0019), recommending the variation of the marketing authorisation to update the product information with the statement on use during pregnancy and lactation. 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 list of outstanding issues to be addressed in writing for a quality, grouped type II variation for **Aivlosin** (EMEA/V/C/000083/II/0062/G).

3.3 Lists of questions

- The Committee adopted the list of questions for a quality type II variation for **Eurican Herpes 205** (EMEA/V/C/000059/II/0017).
- The Committee adopted the list of questions for a quality type II variation for **Hiprabovis IBR Marker Live** (EMEA/V/C/000158/II/0005).
- The Committee adopted the list of questions for a quality type II variation for **Vaxxitek HVT+IBD** (EMEA/V/C/000065/II/0016).
- The Committee adopted the list of questions 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).

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

- There were no items for discussion.

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 considered the notification from France for an Article 78 procedure for **Closamectin pour-on solution and associated names** due to concerns for animal safety, and agreed to start the procedure (EMEA/V/A/113) and appointed M. Holzhauser-Alberti as rapporteur and H. Jukes as co-rapporteur. The Committee adopted the list of questions and the timetable. 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 commercially 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 some recommendations for **Activyl** (EMEA/V/C/000163/REC/004-005-006).
- The Committee adopted the rapporteur's assessment report on the data submitted concerning a condition for **Zulvac SBV** (EMEA/V/C/002781/ANX/004).
- The Committee adopted the rapporteur's assessment report on the data submitted concerning a recommendation for **Nobivac L4** (EMEA/V/C/002010/REC/001).

5.3 Product anniversary list

- The Committee endorsed the product anniversary list for the period between 05/06/2015 – 09/07/2015:

Product	Period
Circovac (EMEA/V/C/000114)	21/06/2014 - 20/06/2015
Convenia (EMEA/V/C/000098)	19/06/2014 - 18/06/2015
Equilis Prequenza (EMEA/V/C/000094)	08/07/2014 - 07/07/2015
Equilis Prequenza Te (EMEA/V/C/000095)	08/07/2014 - 07/07/2015
Equilis Te (EMEA/V/C/000093)	08/07/2014 - 07/07/2015
Equilis West Nile (EMEA/V/C/0)02241	06/06/2014 - 05/06/2015
EQUIOXX (EMEA/V/C/000142)	25/06/2014 - 24/06/2015
ERYSENG (EMEA/V/C/002761)	04/07/2014 - 03/07/2015
ERYSENG PARVO (EMEA/V/C/002762)	08/07/2014 - 07/07/2015
LEUCOFELIGEN FeLV/RCP (EMEA/V/C/000143)	25/06/2014 - 24/06/2015
LEUCOGEN (EMEA/V/C/000144)	17/06/2014 - 16/06/2015
Melovem (EMEA/V/C/000152)	07/07/2014 - 06/07/2015
MS-H vaccine (EMEA/V/C/000161)	14/06/2014 - 13/06/2015
Nobilis IB4-91 (EMEA/V/C/000036)	09/06/2014 - 08/06/2015
Porcilis ColiClos (EMEA/V/C/002011)	14/06/2014 - 13/06/2015

Product	Period
Porcilis Pesti (EMEA/V/C/000046)	09/06/2014 - 08/06/2015
Posatex (EMEA/V/C/000122)	23/06/2014 - 22/06/2015
Poulvac E. coli (EMEA/V/C/002007)	15/06/2014 - 14/06/2015
PRILACTONE (EMEA/V/C/000105)	20/06/2014 - 19/06/2015
Reconcile (EMEA/V/C/000133)	08/07/2014 - 07/07/2015
Vectra Felis (EMEA/V/C/002746)	06/06/2014 - 05/06/2015
Versican Plus DHPPi (EMEA/V/C/003679)	04/07/2014 - 03/07/2015
Versican Plus Pi (EMEA/V/C/003681)	04/07/2014 - 03/07/2015

5.4 Renewals

- 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 the renewal of **BTVPUR AlSap 1** (EMEA/V/C/002230/R/0005), 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 (29 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for the renewal of **BTVPUR AlSap 1-8** (EMEA/V/C/002231/R/0005), 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 (29 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for the renewal of **Meloxoral** (EMEA/V/C/000151/R/0006), 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 01/04/2014 – 31/03/2015 for **COXEVAC** (EMEA/V/C/000155) concluding that no changes to the product literature are necessary at this time point.
- The Committee adopted the CVMP assessment report of the PSUR for the period 01/08/2014 – 31/01/2015 for **Nobivac L4** (EMEA/V/C/002010) with a recommendation to amend the SPC.
- The Committee adopted the CVMP assessment report of the PSUR for the period 01/09/2014 – 28/02/2015 for **Pexion** (EMEA/V/C/002543) with a recommendation to amend the SPC.

- The Committee adopted the following CVMP PSUR assessment reports concluding that no changes to the product literature or other regulatory actions were required at this stage for:

Product	Period
BLUEVAC BTV8 (EMEA/V/C/000156)	01/05/2014 – 31/10/2014
Bovilis BTV8 (EMEA/V/C/000148)	01/10/2014 – 31/03/2015
Bravecto (EMEA/V/C/002526)	01/09/2014 – 28/02/2015
NexGard (EMEA/V/C/002729)	01/09/2014 – 28/02/2015
Proteq West Nile (EMEA/V/C/002005)	01/03/2012 – 28/02/2015
Purevax Rabies (EMEA/V/C/002003)	01/03/2012 – 28/02/2015
Purevax RC (EMEA/V/C/000091)	01/03/2012 – 28/02/2015
Purevax RCP (EMEA/V/C/000090)	01/03/2012 – 28/02/2015
Purevax RCP FeLV (EMEA/V/C/000089)	01/03/2012 – 28/02/2015
Purevax RCPCh (EMEA/V/C/000088)	01/03/2012 – 28/02/2015
Purevax RCPCh FeLV (EMEA/V/C/000085)	01/03/2012 – 28/02/2015
RevitaCAM (EMEA/V/C/002379)	01/09/2014 – 28/02/2015
RHINISENG (EMEA/V/C/000160)	01/04/2014 – 31/03/2015
Semintra (EMEA/V/C/002436)	01/09/2014 – 28/02/2015

- The Committee discussed the CVMP assessment report on the post authorisation safety study for **Parvoduk** (EMEA/V/C/002740). The finalisation of the assessment was postponed to next meeting to allow the marketing authorisation holder to address the proposals made.
- The Committee endorsed the surveillance analysis findings for **ZOLVIX** (EMEA/V/C/000154).
- 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.

- There were no items for discussion.

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

Information relating to certain topics discussed under section 6.1 at this meeting cannot be released at the present time as it is deemed to be confidential.

6.2 Codex Alimentarius

- There were no items for discussion.

6.3 Other EU bodies and international organisations

- The Committee deferred the feedback on EFSA's pesticides peer review meeting on diflubenzuron, held on 27-29 May 2015, to its September meeting.
- The Committee was informed that the report of the Joint European Medicines Agency (EMA)/Heads of Medicines Agencies (HMA) workshop on the requirements for the authorisation of veterinary vaccines in the European Union (EU), held on 25 March 2015, would be published after the HMA meeting.

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 7 July 2015, and noted the agenda of the meeting.

7.2 Quality Working Party (QWP)

- The Committee received a verbal report from the veterinary vice-chair of the QWP on the meeting held on 26-28 May 2015, and noted the agenda of the meeting, the table of decisions and the agenda of the Interested Parties meeting held on 28 May 2015.
- The Committee adopted the concept paper for the revision of the guideline on manufacture of finished dosage form for a 3-month period of public consultation.
- The Committee adopted the concept paper on the need for a single note for guidance on the chemistry of active substances for a 3-month period of public consultation.

7.3 Safety Working Party (SWP-V)

7.4 Environmental Risk Assessment Working Party (ERAWP)

- The Committee received a verbal report from the secretariat of the ERAWP on the meeting held on 16-17 June 2015, and noted the minutes and the agenda of the meeting.

7.5 Efficacy Working Party (EWP-V)

- The Committee received a verbal report from the chair of the EWP-V on the meeting held on 19-20 May 2015.

7.6 Antimicrobials Working Party (AWP)

- The Committee adopted the concept paper on use of extended-spectrum penicillins in animals in the European Union: development of resistance and impact on human and animal health (EMA/CVMP/AWP/37203/2015) for a 3-month period of public consultation.

7.7 Immunologicals Working Party (IWP)

- The Committee received a verbal report from the chair of the IWP on the meeting held on 17-18 June 2015, and noted the agenda of the meeting.
- The Committee adopted the revised draft guideline on requirements for the production and control of immunological veterinary medicinal products (EMA/CVMP/IWP/206555/2010-Rev.1) and the CVMP reflection paper on methods found suitable within the EU for demonstrating freedom from extraneous agents of the seeds used for the production of immunological veterinary medicinal products (EMA/CVMP/IWP/251741/2015), both for a 6-month period of public consultation.

7.8 Pharmacovigilance Working Party (PhVWP-V)

- The Committee received a verbal report from the chair of the PhVWP-V on the meeting held on 30 June – 1 July 2015, and noted the agenda of the meeting.

7.9 Novel therapy groups and related issues

- The Committee received a verbal report from the chair of the ad hoc expert group for veterinary novel therapies from the 2nd core group meeting held on 4 June 2015, and noted the agenda of the meeting.

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 2 June 2015;
- Final minutes of the 74th Joint CHMP/CVMP QWP meeting held on 3–5 February 2015;
- Draft minutes of the EWP meeting held on 19-20 May 2015;
- Final minutes of the IWP meeting held on 26-27 March 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 agreed to include **N-ethylglucamine** as a new entry in the list of substances considered as not falling within the scope of Regulation (EC) No 470/2009 under the heading of excipients, following the request from the applicant.
- 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.30).

8.2 Environmental risk assessment

8.3 Antimicrobial resistance

- The Committee received a verbal report from the meeting of the European Commission Working Group on Antimicrobial Resistance held in Brussels on 1 July 2015.

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 noted the draft minutes of the meeting held on 4-5 June 2015, as well as the draft agenda of the meeting held on 9-10 July 2015.

12. ORGANISATIONAL AND STRATEGIC MATTERS

- The Committee discussed the draft 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 deferred the discussion of the guideline on the principles for preparing assessment reports for veterinary medicinal products and the template guidance to the September 2015 meeting.
- The Committee endorsed the revised CVMP meeting dates for 2016 onwards.

- The Committee agreed to defer the verbal report from the Chair on the meeting of the Scientific Coordination Board on 29 June 2015 to the September 2015 meeting.
- The Committee noted the draft minutes of the CVMP Interested Parties' Meeting held on 6 May 2015.
- The Committee noted the table of actions following the June 2015 CVMP meeting.

13. LEGISLATION

- There were no items for discussion.

14. ANY OTHER BUSINESS

- Upon the completion of the July 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 July 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/0019) • 5.5 PSURs for Pexion and Semintra • 10.2 one item
BE	Bruno Urbain	Full involvement	
BG	Emil Kozhuharov	Full involvement	
DK	Ellen-Margrethe Vestergaard	Full involvement	
EE	Toomas Tiirats	Full involvement	
ES	Cristina Muñoz Madero	Full involvement	
FI	Martti Nevalainen	Full involvement	
HU	Gábor Kulcsár	Full involvement	
IE	David Murphy (vice-chair)	Full involvement	
IT	Maria Tollis	Full involvement	
LU	Marc Schmit	Full involvement	
MT	Stephen Spiteri	Full involvement	
NL	Johan Schefferlie	Full involvement	
PT	João Pedro Duarte da Silva	Full involvement	
RO	Lollita Taban	Full involvement	
SE	Eva Lander Persson	Full involvement	
SI	Stane Srčič	Cannot act as rapporteur or peer reviewer for:	• 2.1 EMEA/V/C/002804/0000
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	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	Frédéric Klein	Full involvement	
CZ	Leona Nepejchalová	Full involvement	
DE	Esther Werner	Full involvement	
EL	Angeliki Tsigouri	Full involvement	
FR	Jean-Claude Rouby	Full involvement	

Country	CVMP Alternate	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
HR	Frane Božić	Full involvement	
NL	Peter Hekman	Full involvement	
PL	Anna Wachnik-Święcicka	Cannot act as rapporteur or peer reviewer for:	• 3.1 Advocate (EMEA/V/C/000076/II/0026/G) • 4.7 one item • 7.1 one item
SE	Frida Hasslung Wikström	Full involvement	
SK	Eva Chobotová	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	Els Dewaele *(remotely)*	Full involvement	
DE	Uta Wolfinger *(remotely)*	Full involvement	
FR	Cedric Colmar	Full involvement	
FR	Michael Holzhauser Alberti *(remotely)*	Full involvement	
FR	Sylvie Louet	Full involvement	
NL	Jacqueline Poot *(remotely)*	Full involvement	
NO	Hanne Bergendahl *(remotely)*	Full involvement	
UK	Giles Davies	Full involvement	
UK	Gillian Diesel *(remotely)*	Full involvement	
UK	Bryan Ward *(remotely)*	Full involvement	

CVMP working parties and CMDv	Chair
AWP	Helen Jukes
CMDv	--
ERAWP	--
EWP-V	Gesine Hahn
IWP	Esther Werner
PhVWP-V	Peter Ekström *(remotely)*
QWP	Piet-Hein Overhaus *(Vet vice chair)*
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