

Work instructions

Title: Organisation of CVMP Working Party meetings		
Applies to: Veterinary Medicines		
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1. Changes since last revision

To incorporate the new unified procedure on working party mailings. All mailings are now distributed via MMD.

2. Records

All documents and correspondence related to the organisation of the relevant WP meeting (incl. completed evaluation forms after CoI evaluation) are saved electronically in the DREAM folder structure: *Cabinets/02b. Administration of Scientific Meeting/WPs SAGs DGs and other WGs/CVMP - xxWP/2. Meeting Organisation/<YEAR>/<Meeting number (date)>*.

3. Instructions

3.1. Scope

The WIN applies to the Veterinary Medicines Division and in particular to the assistants who are responsible for the organisation and distribution of mailings for the relevant CVMP Working Party.

It applies to the following groups:

- CVMP Antimicrobials Working Party (AWP)
- CVMP Efficacy Working Party (EWP-V)
- CVMP Environmental Risk Assessment Working Party (ERA WP)
- CVMP Immunologicals Working Party (IWP-V)

- CVMP Pharmacovigilance Working Party (PhVWP-V)
- CVMP Safety Working Party (SWP-V)

This document does not apply to the CVMP Scientific Advice Working Party and the CVMP Ad Hoc Expert Group on Novel Veterinary Therapies¹.

3.2. Definitions

AST	Assistant (here: assigned to specific Working Party)
AWP	CVMP Antimicrobials Working Party
CoI	Conflict of Interest
CVMP	Committee for Medicinal Products for Veterinary Use
DREAM	Document Records Electronic Archive Management
ECD	Eudra Common Directory
eDoI	Electronic Declaration of Interest
ERA WP	CVMP Environmental Risk Assessment Working Party
Eudralink	Secure electronic e-mailing system
EWP-V	CVMP Efficacy Working Party
HDep	Head of Department
HDiv	Head of Division
HSer	Head of Service
IWP	CVMP Immunologicals Working Party
MMD	Managing Meeting Documents systems
MMS	Meeting Management System (for room bookings)
MMSIII	Meeting Management System (for invitations/mailings)
PhVWP-V	CVMP Pharmacovigilance Working Party
PM	Project Manager; here: SA responsible for a particular WP
SA	Scientific Administrator
SWP-V	CVMP Safety Working Party
WP	Working Party

¹ Please refer to WIN/V/4034 on secretarial tasks for organisation of CVMP Scientific Advice Working Party; or WIN/V/4043 on CVMP ADVENT coordination of core and topic groups, respectively.

3.3. Instructions

Step	Action	Responsibility
1.0	Meeting room booking	
	<i>at least 2 years in advance</i>	
1.1	<p>Book meeting rooms using MMS indicating appropriate Budget Centre:</p> <ul style="list-style-type: none"> • AWP: "V-Special Activities" – "AWP – Antimicrobial Working Party" • ERA WP: "V-Normal Activities" – "CVMP Environmental Risk Assessment" • EWP-V: "V-Normal activities" – "CVMP Efficacy" • IWP: "V-Normal Activities" – "CVMP IWP" • PhVWP-V: "V-Special Activities" – "CVMP Pharmacovigilance" • SWP-V: "V-Normal Activities" – "CVMP Safety" <p>Create one room booking for each meeting, applying the meeting pattern established previously (choose same months, week days, timings and/or similar relation to CVMP meetings/other WPs).</p>	AST
1.2	Propose meeting dates to PM and prepare WP document for endorsement of meeting dates (see "meeting organisation" folder for each working party). Submit to next meeting for endorsement (preferably summer meeting, i. e. endorsement of 2020 meeting dates in summer meeting 2018).	AST
1.3	<p>PhVWP-V only: <i>at the end of the preceding year</i></p> <p>Agree dates with PM and chair for Chair's briefing to be held via Adobe on Thursdays before the meeting, book Adobe connect sessions in MMS, send invitations via outlook to chair, vice-chair, HDep and PM in charge of the WP.</p>	AST
2.0	Meeting Request	<i>at the latest 5 weeks before meeting</i>
2.1	<p>Prepare meeting request in MMS. Check that meeting times are correct and add appropriate number of reimbursed participants² and consult with PM whether any additional reimbursements should be requested for attending experts.</p> <ul style="list-style-type: none"> • AWP: 15 participants (12 reimbursed, 1 expert, 2 EMA); 1st day 13:00-18:00; 2nd day 09:00-16:00 • ERA WP: 14 participants (12 reimbursed, 1 expert, 1 EMA); 1st day 09:00-18:00; 2nd day 09:00-13:30 • EWP-V: 30 participants (25 reimbursed, 1 expert, 1 EMA) 	AST

² For "full" Working Party meetings, like the PhVWP-V and SWP-V, as a general rule this means one reimbursed member per member state (plus one reimbursement for Chairperson); members from Iceland & Norway are also reimbursed.

Step	Action	Responsibility
	<p>1st day 09:00-18:00; 2nd day 09:00-13:00</p> <ul style="list-style-type: none"> IWP: 28 participants (25 reimbursed, 1 expert, 1 EMA) 1st day 09:00-18:00; 2nd day 09:00-13:00 PhVWP-V: 35 participants (28 reimbursed, 4 experts, 3 EMA); 1st day 13:00-17:30; 2nd day 09:00-13:00 SWP-V: 31 participants (28 reimbursed, 2 experts, 1 EMA); 1st day 13:00-18:00; 2nd day 09:00-15:30 	
2.2	Submit meeting request indicating all the required equipment to be available in the particular meeting room and track progress. Make sure that it is signed off fully within one week. Send reminders via MMS, if necessary.	AST
2.3	Check with PM whether any video- and/or phone conference is scheduled for the meeting. If yes, make necessary arrangements (with AV Support, if applicable).	AST
3.0	Check of eDoI <i>before sending invitations</i>	
3.1	Ensure that all WP members and experts have current eDoI forms. If any are outdated, request to update the eDoI following the SOP/EMA/0040 on Evaluation of conflicts of interests of experts for involvement in Agency activities.	AST AST
	Prepare form for PM and ensure that PM has evaluated eDoIs with direct or indirect interests declared. Ensure that new experts are included in European Experts Database.	
4.0	Invitations <i>4 weeks before meeting</i>	
4.1	Prepare invitations for submission in MMSIII. Add participants from ECD by entering the group's abbreviation into the "Add participants from ECD group" field and save the list. Then select "Set ALL reimbursed"; and deactivate "reimbursed" option individually per participant for regularly attending experts (not members) of the group. <i>Make sure that no member or expert is indicated as "industry representative".</i>	AST
4.2	Select "Send invitations", ticking all participants (apart from representative from Liechtenstein, if applicable, who only receives the mailings; and also unticking all participants that have an out of date DoI). <i>Send invitations no later than 3 weeks before the meeting.</i>	AST
4.3	When notified of further experts attending or replacing the member, add them to MMSIII, change the reimbursement status (if applicable) and (re-)send invitation.	AST

Step	Action	Responsibility
5.0	Preparation of Agenda and documents <i>at the latest 3 weeks before meeting or following request from PM</i>	
5.1	<p>Anytime after the post-meeting mailing of the previous meeting was sent out, save a copy of the final agenda in the DREAM folder for next meeting.</p> <p>Also at this time create a folder in MMD for the next meeting by copying a folder structure from the following location: Cabinets/Template Management/Folder Structures/MMD Folder Templates/xWP-V/YYYY-MM xWP-V</p> <p>Make sure that the correct document number and revision number is always shown in the footer.</p> <p><i>Note: for the 1st and 2nd mailing the revision number would be "draft 1" and "draft 2" (etc) until the agenda is adopted at the meeting. Then all "draft" notes are removed and the document number stands alone for the post-meeting mailing. This approach has been agreed between Service Heads and CVMP secretariat and has to be applied consistently.</i></p>	AST
5.2	Add points and documents to the agenda as per requests from PM. Minutes of previous meeting(s); current work programme for reviewing progress; and any other documents that are routinely discussed at every meeting can be added without indication from PM ³ .	AST
6.0	First mailing <i>to be sent 2 weeks before meeting</i>	
6.1	<p>After draft 1 agenda has been agreed with Chairperson (if applicable, in any case after PM indicates that it is ready to be sent), table documents as indicated on the agenda in the relevant WP folder in MMD.</p> <p>For documents not yet available ensure that 'To be circulated' or 'To be tabled' is indicated next to document entry on agenda.</p>	AST
6.2	<p>Re-check eDoI status of experts, send additional reminder to the expert for outstanding eDoI prior to sending out the mailing. If eDoIs have been received since the last check (at invitation stage), ensure risk level has been assessed and, if applicable, send the invitation.</p> <p>Table the documentation package (zip) and make it available in MMD for WP members, as per instruction on 'creating a documentation package in MMD' (available here: <i>Cabinets/02b. Administration of Scientific Meeting/CVMP - Administration/1. Governance/11. Secretariat/Process Improvement/MMD/MMD guidance for CVMP WPs/For secretariats</i>).</p> <p>Send an email to the members of the relevant WP (cc the WP inbox, if available) informing them that the package is now available in MMD for download with the following text:</p>	AST

³ For listings of permanent agenda points for each WP , see Annex I

Step	Action	Responsibility
	<p>-----</p> <p>Dear colleagues,</p> <p>Please be kindly advised that the xx mailing for the xxWP meeting to be held on DD-DD month year is now available in MMD. The zip file containing the mailing documentation is located under the following folder:</p> <p>xxWP - Current Meeting and Archive – 201x</p> <p>MMD is accessible at http://docs.eudra.org/ by using the same user login name and password that you would use for EudraLink.</p> <p>/!\ Members accessing MMD with a Connectra Token, please use the following link: https://access.ema.europa.eu/sslvpn</p> <p>You will find requirements for technical settings of your workstation (laptop/desktop) on the MMD login page.</p> <p>Please remember to use the <u>Table of Content</u> document located under the folders once the zip file is extracted to access documentation of the mailing including the agenda.</p> <p>Within the folder “00. Agenda and organisational issues” you will also find the agenda, which <u>does not contain</u> links, but which can be used for ease of reference.</p> <p>For your convenience please find also attached a guidance that will show you the steps on how to extract the mailing from MMD.</p> <p>As you are aware the documentation can be retrieved from your NCA (so in case you are not inside your Agency please ensure to organise yourself with colleagues who have access to MMD) or if you are working at university etc. by using the Connectra Key.</p> <p>Lastly, we kindly ask you to provide feedback on accessing the documentation via MMD and to contact MMD@ema.europa.eu promptly for any unexpected issues you might have encountered.</p> <p>Kind regards, on behalf of <name of PM> <insert own signature></p> <p>-----</p>	
6.3	After the 1 st mailing has been sent out, change agenda in DREAM to “draft 2” (including the footer). Make sure mailing date is updated (including the footer). When adding new documents to agenda, mark them as NEW or UPDATED .	AST
7.0	Second mailing	<i>to be sent 1 week before meeting</i>

Step	Action	Responsibility
7.1	<p>Update the agenda with regard to new/additional points or documents.</p> <p>For documents not yet available ensure that <i>'To be tabled'</i> is indicated next to document entry on agenda.</p> <p>Table any new/updated documents in the relevant MMD folder.</p>	AST
7.2	<p>Table the documentation package (zip) and make it available in MMD for WP members as per instruction for sending the 1st mailing.</p> <p>Send an email to members of the relevant WP (cc the WP inbox, if available) informing them that the package is now available in MMD for download.</p> <p>Use the same text in the email as when sending the 1st mailing, updating the text as necessary.</p>	AST
7.3	<p>Include agenda in the CVMP agenda for information under the relevant Working Party entry under point 7.</p>	AST
7.4	<p>Change agenda in DREAM to "draft 3" (including the footer). Make sure date of 1st day of meeting is indicated (including the footer). Remove all "New" and "Update" markings from 2nd mailing. When adding new documents to agenda, mark them as NEW or UPDATED. <i>This time the markings will be kept continuously for the final mailing.</i></p>	AST
8.0	Tasks during week before meeting	
8.1	<p>Prepare template for minutes for the meeting on the basis of the agenda in meeting folder in DREAM and copy it into G:\drive (G:\SharedAreas\Mailings\V\[relevant WP folder]) for PM to fill in during the meeting, inserting all agenda points, standard phrases around the text of the agenda point and the documents numbers in brackets.</p>	AST
8.2	<p><i>No later than 2 working days before the meeting:</i></p> <p>Send Visitor Request form (right-hand side navigation on Intranet) to Reception indicating industry attendance, if required. <i>Only participants not listed in MMSIII need a visitor request, everyone in MMSIII is automatically in the system.</i></p>	AST
9.0	Before/during meeting⁴	
9.1	<p>Print list of participants for PM (from MMSIII or last page of minutes – completed according to attendance notified in MMS or by email). Highlight members with eDoI direct or indirect interests declared, and new members. Print additional copy for Chairperson, if requested by PM.</p> <p><i>Exception: PhVWP-V list of participants is sent to PM and Chairperson before the Chair's briefing (usually Thursday before meeting).</i></p>	AST

⁴ If meeting starts in the morning, sets for tabling should be prepared and the room should be set up on the day before the meeting; otherwise these actions apply to the morning of the 1st day of the meeting.

Step	Action	Responsibility
10.0	Final mailing <i>to be sent 1 week after the meeting</i>	
10.1	Prepare agenda and additional documents that were tabled before and during the meeting for final electronic mailing; as well as any post-meeting updates, if applicable.	AST
10.2	<p>Save agenda adding "Final agenda" in the version label of the document in DREAM (major revision).</p> <p>Table any new/updated documents in the relevant MMD folder.</p> <p>Table the documentation package (zip) and make it available in MMD for WP members as per instruction for sending the 1st and 2nd mailing.</p> <p>Send an email to members of the relevant WP (cc the WP inbox, if available) informing them that the package is now available in MMD for download.</p> <p>Use the same text in the email as when sending the previous mailings, but update the text, as necessary</p>	AST
10.3	Make sure that the archive folder is complete (including documents tabled during the meeting and additional updates for the final mailing).	AST
10.4	Include final agenda in the CVMP agenda for information under the relevant entry under point 7.	AST
11.0	Minutes and table of actions	
11.1	Following agreement of the draft minutes with the Chairperson of the group, assist PM in drafting the ToA from the minutes (if PM wishes).	AST
11.2	Circulate minutes (and ToA, if applicable) to group, as usual.	AST
11.3	Include minutes in the CVMP agenda for information under relevant WP in section point 7.	AST
12.0	End of procedure	

Annex I

Lists of permanent agenda points

AWP

- i – Agenda (correct document reference number)
- ii – Declaration of Conflicts of Interest
- iii – draft minutes of previous meeting (put correct numbers and link minutes)
- 1.1 – Update on current activities
- 1.2 – CVMP: Report from Chairperson of AWP
- 5 Organisational issues – Review of progress with work programme
- 5 Organisational issues – Updated contact details
- End of agenda – update next meeting dates

ERA WP

- 0 – Agenda and organisational issues
 - Conflicts of interests
 - Adoption of the agenda
 - Adoption of the summary record for the meeting
 - CVMP
- 1 Regulatory related issues
- 2 Guidelines
- 3 Concept papers
- 4 Reflection papers
- 5 Workshops and training
- 6 Miscellaneous
- 7 Organisational issues
- 8 Any other business
- End of agenda – update next meeting dates

EWP-V

- 0 Draft agenda and summary record – Draft agenda and Reminder to declare conflicts of interests with regard to agenda items / Minutes of the previous meeting
- 1 Regulatory issues – List of guidelines (EMA/CVMP/EWP/60218/2005)
- 2 (End of point) – Revised documents – for discussion/adoption
- 3 VICH: Status of VICH guidelines (EMA/CVMP/28625/2005)
- 4 Organisational issues – Review of progress with work programme
- 4 Organisational issues – List of EWP members; make sure that document in DREAM is up to date and copy it to G:\drive
- 4 Organisational issues – Table of Actions
- End of agenda – update next meeting dates

IWP

- 0 Draft agenda (correct document reference number), Declaration of conflicts of interests draft minutes of previous meeting (put correct number and link minutes), matters referred from the CVMP and actions arising from the previous meeting and update on various issues from EMA/IWP secretariat
- 1 Guidelines and recommendations
- 2 Topics for discussion
- 3 Co-operation with other EU or international bodies
- 3.1 EDQM
- 3.2 VICH
- 3.3 EFSA
- 4 Other EMA Working Parties and Scientific Advisory Groups

- 4.1 CVMP
- 4.2 Scientific Advice Working Party-V
- 4.3 JEG 3Rs
- 4.4 CHMP Biologics Working Party
- 4.5 Safety Working Party
- 5 Organisational matters – Review of progress with work programme
- 6 AOB - Next meetings of the CVMP Immunologicals Working Party

PhVWP-V

- 0.1 Declaration of conflicts of interests
- 0.2 Agenda (correct document reference number)
- 0.3 Summary record
- 1 Report from CVMP, CVMP Strategic Planning Group, HMA-V
- 2 Monitoring of adverse events, rapid alerts and non urgent information
 - Point 2.1 – Centrally authorised products
 - Point 2.2 – Nationally authorised products
 - Point 2.3 – Drug monitor summarising rapid alerts and the non urgent information system
- 3 Requests for advice
 - Point 3.1 – CVMP
 - Point 3.2 – Member States
- 4 Pharmacovigilance systems and inspections
- 5 Regulatory issues
 - Point 5.1 – Legal framework
 - Point 5.2 – Implementation of legislation and development of guidance
 - Point 5.3 – VICH
- 6 Organisational matters and general issues: review of progress with work programme
- Documents for information – e. g. adopted PSUR assessment reports from previous 2 CVMP meetings; status report on PSURs; updated contact list

SWP-V

- 0 – Agenda and organisational issues
 - Conflicts of interests
 - Adoption of the agenda
 - Adoption of the summary record for the meeting
 - CVMP
- 1 Substance related issues
- 2 Regulatory issues [Guidelines, concept papers ...]
- 3 VICH
- 4 Codex Alimentarius / JECFA
- 5 Organisational issues
- 6 Miscellaneous
- 7 Any other business
- End of agenda – update next meeting dates

Annex II - Handling of new experts/members or contact detail changes

Databases / documents used:

ECD	http://ecdm.eudra.org/ecdm20/portals/std/index-portal.jsp
PhVWP-V contact list	Cabinets/02b. Administration of Scientific Meeting/WPs SAGs DGs and other WGs/CVMP - PhVWP/1. Governance/04. Memberships
SWP-V contact list	Cabinets/02b. Administration of Scientific Meeting/WPs SAGs DGs and other WGs/CVMP - Safety WP/1. Governance/04. Memberships
ERA contact list	Cabinets/02b. Administration of Scientific Meeting/WPs SAGs DGs and other WGs/CVMP - ERAWP/1. Governance/04. Memberships
AWP contact list	Cabinets/02b. Administration of Scientific Meeting/WPs SAGs DGs and other WGs/CVMP - AWP/1. Governance/04. Memberships
EWP-V contact list	Cabinets/02b. Administration of Scientific Meeting/WPs SAGs DGs and other WGs/CVMP - EWP/1. Governance/04. Memberships
IWP contact list	Cabinets/02b. Administration of Scientific Meeting/WPs SAGs DGs and other WGs/CVMP - IWP/1. Governance/04. Memberships

First steps

1. Check expert status
2. Tell your colleagues
3. Send an email to ECD managers requesting them to change information about a relevant person or requesting a new entry in the ECD.

Full Contact lists

There are currently full contact details lists in existence for SWP-V, PhVWP-V, ERA WP, EWP-V, AWP and IWP (see beginning of this instruction for respective locations). The lists are maintained by the Vet Assistant responsible for that group. Make changes in the list for your group, as required. Generally, do not edit the list of a group that you are not the main responsible person for, but rather inform the Assistant of that group of the changes.

Annex III - Checklist⁵ for meeting organisation

At the latest 5 weeks before meeting	
<input type="checkbox"/>	Ensure meeting room is booked. (Step 1.1)
<input type="checkbox"/>	Initiate meeting request in MMS. (Step 2.1)
<input type="checkbox"/>	Follow-up approval in MMS; ensure process is final approx. 4 weeks before meeting (Step 2.2)
<input type="checkbox"/>	Check need for phone or video conference during meeting. (Step 2.3)
4 weeks before meeting/before sending the invitations	
<input type="checkbox"/>	Set up meeting in MMSIII (Step 3.1)
<input type="checkbox"/>	Check MMSIII for status of DoI of all participants. (Step 3.2)
<input type="checkbox"/>	Evaluate risk levels 2 or 3, if applicable (Step 3.3)
4 weeks before meeting (no later than 3 weeks before)	
<input type="checkbox"/>	Prepare invitations in MMSIII. (Step 4.1)
<input type="checkbox"/>	Send invitations (no later than 3 weeks before the meeting). (Step 4.2)
	Invitations sent on _____
<input type="checkbox"/>	Inform MMC of any required invitations for observers from candidate countries. (Step 4.3)
<input type="checkbox"/>	Set up archive meeting folder. (Step 4.4)
<input type="checkbox"/>	Process additional expert attendance (or replacements) as notified by members. (Step 4.5)
At the latest 3 weeks before meeting	
<input type="checkbox"/>	Prepare agenda. (Steps 5.1 and 5.2)
<input type="checkbox"/>	Add documents as requested by PM; and recurring discussion items (Step 5.3)

⁵ Checklist to be used in conjunction with WIN/V/4029 – all steps are explained in detail in the WIN.

2 weeks before the meeting	
<input type="checkbox"/>	Check agenda thoroughly & finalise for mailing (Step 6.1)
<input type="checkbox"/>	Send electronic mailing (Step 6.2) 1st mailing sent on _____
<input type="checkbox"/>	Prepare agenda for 2 nd mailing (Step 6.3)
1 week before the meeting	
<input type="checkbox"/>	Check agenda thoroughly & finalise for mailing (Step 7.1)
<input type="checkbox"/>	Send electronic mailing (Step 7.2) & print tracking log for records. 2nd mailing sent on _____
<input type="checkbox"/>	Include agenda in CVMP agenda for information (Step 7.3)
<input type="checkbox"/>	Agenda included in CVMP mailing on _____
During week before the meeting	
<input type="checkbox"/>	Prepare template for minutes (Step 8.1)
<input type="checkbox"/>	At the last 2 days before meeting: send visitor request form for any industry attendance (Step 8.2)
Day before / morning of / during meeting	
<input type="checkbox"/>	Print list of participants for PM (Step 9.1)
1-2 weeks after meeting	
<input type="checkbox"/>	Check agenda thoroughly & finalise for post-meeting mailing (Step 10.1)
<input type="checkbox"/>	Send electronic mailing (Step 10.2) post-meeting mailing sent on _____
<input type="checkbox"/>	Finalise archive folder with revised documents (Step 10.3)
<input type="checkbox"/>	Include final agenda in CVMP mailing for information (Step 10.4) Agenda included in CVMP mailing on _____
<input type="checkbox"/>	Draft ToA from agreed minutes, if applicable (Step 11.1)

<input type="checkbox"/>	Circulate minutes (and ToA, if applicable) via MMSIII (Step 11.2)
<input type="checkbox"/>	Include minutes in CVMP agenda for information (Step 11.3)
	Minutes included in CVMP mailing on _____