

# **International Pharmaceutical Regulators Programme**

## **Standard Operating Procedures of the Management Committee and the Working Groups**

Version 1.1 - dated 2 June 2019  
Approval by the Management Committee on 2 June 2019

## Document History

<b>Version number</b>	<b>Action</b>	<b>Date</b>
<b>v1.1</b>	The MC approved an amendment to section 2.2.4 for rules on engaging external stakeholders and a minor amendment to the Annex 1 of the SOP.	<b>2 June 2019</b>
<b>v1.0</b>	The MC approved the first version of the SOP.	<b>31 July 2018</b>

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## **Standard Operating Procedures Overview**

Further to the Terms of Reference (ToR), these Standard Operating Procedures (SOP) of the Management Committee (MC) and Working Groups (WGs) are intended to provide guidance and interpretation in respect of the provisions of the ToR relating to the MC and WGs, as well as additional detailed operational procedures for the MC and WGs.

In the event of discrepancy or inconsistency between the SOP and the ToR the latter will prevail. In such a case, the SOP should be amended to ensure that they are consistent with the ToR. These SOP, in addition to the ToR, shall be published on the website of the IPRP.

## **1. Management Committee Procedures**

### **1.1. Management Committee membership**

As per the Terms of Reference, membership within IPRP is inclusive and eligible parties can submit an expression of interest to join the IPRP to the Secretariat for consideration by the MC. In general, regulatory parties are invited to join IPRP as a member; however, in exceptional circumstances, at the request of the applicant, or through a determination by the MC, a party may be designated as an observer. The expression of interest should state whether the organisation wishes to join the MC as member or observer and provide the name and contact details of the representative(s). The MC shall take a decision on the membership/observership request.

Parties shall nominate between one and three representative(s). One of the representatives should be delegated as the primary point of contact whose role is to assist in the efficient operation of IPRP activities, act as the primary point of contact with the Secretariat and facilitate conversation between the MC and the Working Groups as needed. Furthermore, parties may nominate alternates and additional support staff. Additionally, the representatives nominated should actively participate in the meetings and contribute to the work of the MC.

### **1.2. Management Committee Chair and Vice-Chair**

As per the Terms of Reference, the MC members and observers shall elect a MC Chair and MC Vice-Chair for a term of 1 year which may be renewed up to three times. Nominations for Chair and Vice-Chair should be submitted in writing by the members and observers, specifying the name of the representative who is put forward as the candidate to the Secretariat no later than one-week in advance of the start of the face-to-face meeting at which the election is to take place.

The decision on the nomination of the MC Chair and Vice-Chair shall be adopted by consensus. Only when consensus cannot be reached, the decisions on the nomination of the MC Chair and Vice-Chair shall be adopted by simple majority of the votes cast and by secret ballot.

It is at the discretion of the member or observer whose representative has been appointed as Chair or Vice-Chair to decide whether or not it wishes to appoint another representative to represent itself in the MC.

### **1.3. Management Committee meetings**

The MC will hold its meetings in conjunction with the ICH meetings. In addition, the MC may hold virtual meetings in the form of tele/web-conferences. The Chair of the MC should propose to the MC the frequency of such virtual or any other meetings for its agreement. The meetings would be set up by the Secretariat at dates and times that are agreed by the MC.

As regards the attendance for face-to-face meetings, the delegation for each party shall consist of up to three representatives and may be accompanied by additional participants, who would be accommodated at or behind the meeting table as space permits. A party is considered to be present if at least one of its representative(s) is present at the meeting, or at least one alternate if none of its representative(s) is able to attend.

The agenda for the meetings shall be prepared by the Secretariat. Following review by the MC Chair and Vice-Chair, the agenda and major background document package should be shared with the MC at least three weeks ahead of a face-to-face meeting and two weeks ahead of a virtual meeting.

External experts may be consulted on an ad-hoc basis on topics for consideration by the MC. A member or observer of the IPRP requesting permission for an external expert to attend an MC meeting shall provide a written request to the IPRP Secretariat before the meeting, asking for the MC to endorse their attendance.

#### **1.4. Management Committee decision-making**

As per the Terms of Reference, a quorum is required for the MC to take decisions. Additionally, while the MC may take some minor decisions electronically, including with respect to the organisation of meetings, in general major decisions including the approval of major documents such as strategy documents shall be made at face-to-face meetings. In exceptional circumstances, major decisions including the approval of major documents can be made at virtual meetings if an initial discussion has already taken place at a face-to-face meeting. An exception is the agendas and reports of the virtual and face-to-face meetings as well as WG documents and publications that can be approved electronically.

The adopted decisions will be recorded in the reports of the MC meetings, to be prepared by the Secretariat. Draft reports should be sent to all MC representatives, following review by the MC Chair and Vice-Chair. Generally, the draft reports should be shared with the MC within two weeks of a meeting for a two-week comment period. If comments are received, the revised reports will be re-circulated for a two-week comment period. If no comments are received at the end of the extended commenting period, the reports shall be considered as adopted.

Where issues or questions arise where the Secretariat considers input from the MC may be needed, the Secretariat shall consult the Chair who will use his/her discretion to provide direction to the Secretariat on the course of action where the issue or question is not sensitive or controversial; or decide that an action should be put on the agenda of the next scheduled MC meeting.

## **2. Working Group Procedures**

### **2.1. Working Group membership**

#### **2.1.1. Establishment of a new Working Group**

All parties can propose new topics to be addressed by IPRP. The proposals should be submitted to the Secretariat who will share the proposal with the MC for endorsement at a face-to-face meeting. The MC should consider whether there is capacity to add a new WG or whether any of the existing groups should finish their work and be disbanded before setting up a new one. Once a proposal has been approved, a WG is established and the Secretariat will conduct a call for nomination of experts.

#### **2.1.2. Appointment of Working Group Chair and co-Chair or Vice-Chair**

The MC officially designates a Chair and a Vice-Chair or two co-Chairs from different IPRP parties amongst members of the WG. In general, the party who proposed the topic would assume the initial

Chairmanship; however, if this party is unable to fill this role, then another expert from the WG could be nominated as Chair. Appointment of the Chair and Vice-Chair or co-Chairs is for 2 years, renewable at the discretion of the MC. Alternatively, the MC may decide to approve the principle of a rotating Chairmanship between MC Members and Observers.

The role of the Chair/Co-Chairs is to facilitate and manage the activities of the WG, reconciling differences of opinion, in order to produce documents/deliverables that is in accordance with the MC's decisions and expectations. The role of the Vice-Chair, if any, is to work in close collaboration with the Chair to support her/his work.

Responsibilities of the Chair/co-Chairs include in particular developing a detailed Work Plan in collaboration with the WG members that will achieve the objectives outlined in the Mandate document approved by the MC, maintaining a record of participation of the experts nominated to the WG, and day-to-day management of the WG including organising (scheduling and hosting) teleconferences of the WG, setting deadlines, assigning work to the experts, monitoring progress and assuring all parties' views are incorporated into documents and presentations as appropriate, as well as addressing the behavior of any expert that is disruptive or not constructive, in consultation with the primary point of contact (see Annex 1 – Guidance for conducting WG 's activities).

The Chair (or Vice-Chair if not available)/co-Chairs shall regularly present reports to the MC on the document(s)/work under development, and at least twice a year during the MC's face-to-face meetings. The report can be given by teleconference if they are not in attendance at the meetings.

### **2.1.3. Appointment of Experts**

The parties that wish to appoint experts in WGs should notify the Secretariat of the names and other contact details of the experts and specify the WG to which the experts are appointed. The parties should inform the Secretariat of any change of experts or the withdrawal of experts.

Once a party has appointed an expert to a WG, this expert is encouraged to actively participate in and contribute to the work of the WG on a continuous and regular basis.

### **2.1.4. Appointment of Project Manager**

The WG may nominate someone to serve as a Project Manager to assist in the ongoing operations of the WG such as note taking, scheduling of meetings, agenda development, capturing agreements and outcomes of discussions, etc.

### **2.1.5. Appointment of other participants**

To support the work of the WG, each party may appoint additional support staff to assist with the preparation of that party's contributions to the WG. Their names and other contact details should be submitted to the Secretariat for inclusion on emails for the WG. These additional staff would work outside of the WG sessions in their support of ongoing operations of the WG.

In the case that external expertise may be helpful, a WG may consider inviting a limited number of liaisons from an entity (e.g. a scientific or technical expert from a university or research institute) to participate in the WG on an ad-hoc basis to provide additional technical expertise. Subject to MC approval, regulatory parties that are not Members or Observers of IPRP may nominate representatives to participate as observers in WGs.

## **2.2. Working Group activities**

### **2.2.1. Development of the Mandate document**

Once a WG is assembled, the WG will be responsible for developing a Mandate document describing in details the remit of the WG and date of endorsement by the MC. The Mandate document will also include general considerations, objectives, scope of the activities, and participating parties. The development of the Mandate document is led by the Chair/Co-Chairs with input from the entire WG. The Mandate document should follow the template provided in Annex 2.

The Mandate document shall be submitted to the MC for endorsement prior to initiation of any work activity. It should be re-evaluated at least once a year ahead of the second face-to-face meeting of the MC and updated as needed. The Mandate document for each WG will be posted on the IPRP Public Website.

### **2.2.2. Development of the Work Plan**

Once a WG is assembled and along with the development of a Mandate document, the WG will be responsible for developing a detailed Work Plan prior to initiation of any work activity. The development of a Work Plan is led by the Chair/co-Chairs with input from the entire WG. The Work Plan should include a statement of the proposed work product(s) to be delivered, anticipated milestones and timeline for completion, topics lead(s), summary of recent activities and current statuses of the work product(s), any requests for endorsement by the MC, any requests to meet. The Work Plan should follow the template provided in Annex 2.

The Work Plan shall be submitted to the MC for endorsement prior to initiation of any work activity. It should be updated as needed and at least once a year ahead of the second face-to-face meeting of the MC for endorsement by the MC. The Work Plan for each WG will be posted on the IPRP Public Website.

Furthermore, the WG should provide a report, either in-person or via web or teleconference, to the MC at each face-to-face meeting of the MC on the progress and status of the activities undertaken. The Chair/co-Chairs of each WG will be invited to join the MC meeting to provide this report either in person or remotely (by web or teleconference) by the Secretariat. The Chair/co-Chairs should work with the Secretariat to find an appropriate time for the report to the MC taking into consideration time zone differences with the location of the MC meeting.

### **2.2.3. Approval and publication of documents**

The deliverables produced by the WG in accordance with the Mandate document and Work Plan, including any deliverables for publication, shall be provided to the Secretariat by the Chair/co-Chairs following approval by the WG. The deliverable shall then be submitted to the MC for endorsement and subsequent publication on the IPRP public website, if applicable.

### **2.2.4. Conduct of meetings**

WGs shall conduct their work via e-mail and tele/web conference and if necessary via face-to-face meetings. Should a WG need to conduct a face-to-face meeting, the Chair should make a request to the MC via the Secretariat including a detailed rationale and expected deliverables and the MC should take a decision on a case-by-case basis. Requests for face-to-face meetings should preferably be



submitted to the MC a minimum of 3 months in advance of the proposed meeting dates. Additionally, a WG may receive standing approval from the MC to meet face-to-face on a regular schedule for a defined period. The organization and administration of any face-to-face meeting is within the responsibility of the WG. The meeting agenda and report shall be shared by the Chair/co-Chairs with all experts of the WG prior to and following the meeting.

Interactions of the WGs with external stakeholders are subject to MC approval. In particular, a WG may consider organising a dedicated stakeholder event after its WG meeting to present and discuss activities of the WG to/with external stakeholders, in line with the applicable Terms of Reference and the stakeholder engagement objectives and principles outlined in the IPRP External Stakeholder Engagement Plan. The Chair/co-Chairs shall submit a request to the MC at least 3 months prior to the event for MC endorsement and all presentations should be shared with the MC at least 2 weeks prior to the event.

### **3. Communication**

#### **3.1. Public Statement**

Following an IPRP MC meeting, a public statement shall be issued in order to inform external stakeholders on the work and activities of IPRP and on the outcome of the meeting. The Secretariat is responsible for drafting the public statement along with the MC Chair and Vice-Chair. The draft public statement should be shared with the MC for tacit approval prior to publication on the IPRP website, ideally no later than two weeks after the meeting.

#### **3.2. Transparency**

The following documents shall be published on the IPRP website: Terms of Reference, Standard Operating Procedures, Strategic Vision, public statements, up-to-date Mandate document and Work Plan for each WG, publications by WGs.

#### **3.3. Confidentiality**

The MC representatives, alternates and support staff as well as WG experts are expected to hold all confidential information they receive or that is otherwise brought to their attention in confidence, even after their duties have ceased. In particular, experts are expected to maintain confidentiality of the issues discussed within their WG. Parties should not use the confidential information for any purpose other than as necessary to enjoy their rights or perform their obligations within the IPRP. For the avoidance of doubt, confidential information includes draft documents and proposals pending approval by the MC, in addition to other information shared by IPRP parties not in public domain.

Parties are permitted to present on the IPRP at a public meeting or conference. If a party wishes to present on the ongoing work of a WG, the slides for such presentations should be shared with the WG for any concern ahead of the presentation. The positions of individual parties should not be disclosed. Additionally, if there are issues that the WG has not yet reached consensus on, these issues should not be discussed in detail in a public forum. Also, it should be made clear that the views expressed are not those of the IPRP.

### **3.4. Use of the IPRP logo**

Apart from official use of the IPRP logo by the IPRP MC, or for illustrative purposes, use of the logo requires the express permission of the MC Chair and Vice-Chair. As a general rule, permission shall be granted for use of the IPRP logo on materials which IPRP supports, or for use in the promotion of events IPRP has expressly agreed collaboration on.

It should be noted that this restriction regarding the use of the IPRP logo extends to the use of the IPRP presentation template which carries the logo, with such presentations being subject to the same review and permission process stated above.

## **Annex 1: Guidance on the conduct of Working Groups activities**

### **1. Conduct of Meetings (virtual or face-to-face)**

- a. The agenda and materials to be presented at a meeting should be shared at least one week prior to the meeting with all experts of the WG and the MC via the document-sharing platform.
- b. Meetings should be conducted in the most efficient manner possible. All participants will act in a respectful and professional manner. Excessive posturing by any party should be avoided.
- c. Meeting minutes shall be recorded to summarize key topics of discussion, including substantive proposals, and any significant controversies or differences of opinion, and their resolution, as well as to develop a plan for next steps.
- d. The IPRP Secretariat will conduct the initial call for nomination of experts and maintain the membership list of the WG according to requests received. The IPRP Secretariat will regularly provide the Chair/co-Chairs with the updated membership list of the WG; however, the Chair/co-Chairs should track attendance of experts for each meeting.
- e. The Chair/co-Chairs should ensure that the opinions of all parties are expressed and that the discussion remains in scope of the approved Mandate Document.

### **2. Participation**

- f. All experts to a WG are encouraged to actively participate in and contribute to the work of the WG on a continuous and regular basis until the work is completed to ensure continuity.
- g. Actions or behaviors which seriously impair the proper functioning of the WGs should be avoided. For example, engaging in political, nationalist, propagandist, private profit-oriented or other behavior which is extraneous and detrimental to the technical scientific scope and mission of IPRP. This may also include intimidating behavior and other uncivil or disrespectful treatment of the IPRP Secretariat or IPRP parties, and their staff and expert representatives. It can also include seeking to exert pressure and undue influence on the IPRP Secretariat or IPRP parties by pursuing financial, political, diplomatic, or other channels outside of IPRP.

## Annex 2: Templates

### 1. Mandate Document template

#### MANDATE DOCUMENT <NAME OF THE WORKING GROUP>

##### 1. General Considerations

###### 1.1. Statement of the Perceived Problem

*Please briefly describe what problem(s)/issue(s) the group is expected to tackle, what are the costs (social/health and financial) to our stakeholders associated with the current situation or associated with “non-action”.*

###### 1.2. Expected Benefits

*Please briefly describe what the likely benefits (social, health and financial) of the fulfilment of the objective would be to our stakeholders.*

###### 1.3. Background to the proposal

*Please briefly provide any further relevant information, e.g., the origin of the proposal, references to publications, and discussions in other fora.*

##### 2. Scope

*Please briefly describe the scope of the work proposed, and also anything that is specifically out of the scope.*

##### 3. Objectives

*Please list the main objectives of the work of the group (1-5 main objectives). All deliverables will be further detailed in the work plan.*

- Objective 1: TITLE

Description...

- Objective 2: TITLE

Description...

- ...

##### 4. Composition

*Please list the proposed composition of the group (parties), including the Chair and any Co-Chair or Vice-Chair.*

## **5. Specific organisation**

### **5.1. Designation of a Project Manager**

*Please inform if a Project Manager is expected to provide support services, and if so list its responsibilities (setting up teleconferences and organising meetings, writing agendas and reports, etc).*

### **5.2. Organisation of meetings**

*Please inform if any face-to-face meetings are expected and the frequency, as well as the expected frequency of teleconferences.*

### **5.3. Contact with stakeholders**

*Please provide details on any communication expected with external stakeholders, e.g. symposiums, etc.*

## 2. Work Plan Template

### WORK PLAN <NAME OF THE WORKING GROUP>

**Date:** DD MMMM YYYY

**Chair:** First Name, Last name, Party

**Co-Chair:** First Name, Last name, Party

**Vice-Chair:** First Name, Last name, Party

### 1. Key Milestones and Deliverables

#### 1.1. Current status of key milestones and deliverables

*Please provide in the table below for context the relevant past achieved key milestones and deliverables (recommended 1 – 6 milestones): e.g. final documents, publications...*

Past completion date	Objective	Key Milestone or Deliverable
MMMM YYYY		Short title of the deliverable
MMMM YYYY		Short title of the deliverable
MMMM YYYY		Short title of the deliverable

#### 1.2. Future anticipated key milestones and deliverables

*Please provide in the table below the main deliverable(s) to be achieved in the next year(s) (recommended 3 – 6 milestones): e.g. final documents, publications...*

Expected future completion date	Objective	Key Milestone or Deliverable
MMMM YYYY		Short title of the deliverable
MMMM YYYY		Short title of the deliverable
MMMM YYYY		Short title of the deliverable

### 2. Timeline for Specific Tasks

*Please provide in the table below short-term high-level specific tasks for work to be done within the Working Group in the coming year (recommended 4 – 10 tasks): e.g. teleconferences, meetings, progress on documents...*

<b>Beginning date</b>	<b>End date</b>	<b>Task / Activity</b>	<b>Details</b>
MMMM YYYY	MMMM YYYY	<i>Task/Activity such as: internal consultation, teleconference, review, stakeholder engagement, training, etc...</i>	<i>Brief summary of task/activity objectives and targeted outcome</i>
MMMM YYYY	MMMM YYYY	<i>Task/Activity such as: internal consultation, teleconference, review, stakeholder engagement, training, etc...</i>	<i>Brief summary of task/activity objectives and targeted outcome</i>
MMMM YYYY	MMMM YYYY	<i>Task/Activity such as: internal consultation, teleconference, review, stakeholder engagement, training, etc...</i>	<i>Brief summary of task/activity objectives and targeted outcome</i>
MMMM YYYY	MMMM YYYY	<i>Task/Activity such as: internal consultation, teleconference, review, stakeholder engagement, training, etc...</i>	<i>Brief summary of task/activity objectives and targeted outcome</i>

### **3. Summary of Any Current Issue**

*If relevant, please provide here a summary of any current challenging points which should be raised for the information of the IPRP Management Committee, or on which IPRP Management Committee guidance is needed.*

### **4. Necessity for face-to-face meeting**

*If relevant, please present here the justification of the consensus view of the WG on the necessity for the group to meet face-to-face, in line with the work plan presented above, and provide details on the planning for the meeting(s) and work to be undertaken there.*