# International Pharmaceutical Regulators Programme

## Terms of Reference

Version 1.2 - dated 2 June 2019
Approval by the Management Committee on 2 June 2019

## Document History

| Version number | Action | Date |
|---|---|---|
| **v1.2** | The MC approved a minor edit to section "Objectives" for consistency with the stakeholder engagement plan. | **2 June 2019** |
| **v1.1** | The MC approved a minor edit to section Governance and Management of the Terms of Reference | **31 July 2018** |
| **v1.0** | The MC approved the first version of the Terms of Reference. | **3 June 2018** |

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## PURPOSE

The purpose of the IPRP is to create an environment for members and observers to exchange information on issues of mutual interest and enable regulatory cooperation. This dedicated venue will assist in maximising potential efficiencies in addressing the increasingly complex global regulatory environment, facilitate the implementation of ICH and other internationally harmonised technical guidelines for pharmaceuticals for human use, promote collaboration and regulatory convergence, and contribute to the coordination of a range of international efforts related to regulation of medicinal products for human use.

## GOALS

The IPRP provides members and observers a unique opportunity to leverage expert scientific knowledge, regulatory and operational experience, on-going technical harmonisation activities, and information exchange from a broad range of regulatory bodies. The first goal of IPRP is to share knowledge and information about ongoing work in respective regions and jurisdictions and to identify and develop new approaches, best practices, and strategies to deal with the challenges of a rapidly evolving globalised pharmaceutical industry. The second goal is to provide a global overview of regulatory developments at national and international levels and enable open sharing of information and ideas among regulatory leaders with hands-on operational responsibilities. The third goal of IPRP is to support international pharmaceutical regulatory cooperation in areas that are not covered by existing initiatives.

## OBJECTIVES

Objectives of the IPRP include the following:

I. *Information-sharing*

1. Practical and operational information-sharing through open discussions to enable the sharing of best practices including identification of existing synergies and commonalities on high priority regulatory issues; and
2. Identification and discussion of issues surrounding a common need for the development of:
    a. Effective regulatory strategies,
    b. Better information on specific issues, or
    c. Enhanced training, e.g., for regulatory staff, to address specific issues.

*II. Regulatory convergence*

1. Identify existing differences, synergies and commonalities in regulatory practice to promote regulatory convergence, cooperation and best practices in identified topics which are not duplicative of existing processes or collaborative initiatives;

2. Support the implementation of ICH and other internationally harmonised technical guidelines for medicinal products for human use;
3. Promote common terminologies, definitions and understandings in scientific terms and approaches; and
4. Identify needs for harmonisation or convergence in specific areas (to improve regulatory oversight in a global environment) and propose topics to other international organisations as appropriate.

*III. External engagements and communications*

1. Encourage engagement and seek input from stakeholders, where appropriate; and
2. Provide open and transparent communication to stakeholders through the publication of organisation outcomes and documents as appropriate (e.g. publication on the website).

## SCOPE OF ACTIVITIES

The IPRP will engage in regular discussions related to the objectives outlined above. The products covered are medicinal products for human use ("pharmaceuticals") including but not limited to: innovator pharmaceuticals, cell and gene therapies, biosimilars, biologics, generic pharmaceuticals[1], and nanomedicines. Sample discussion topics might include scientific and technical requirements related to the safety, efficacy or quality of pharmaceuticals for marketing authorisation; regulatory oversight of clinical trials and manufacturing issues; electronic data strategies; and other issues of emerging concern.

The members and observers participate in IPRP activities on a voluntary basis.

## MEMBERSHIP

The membership of IPRP is comprised of representatives from pharmaceutical regulatory authorities and organisations with responsibilities for the regulation of medicinal products for human use or Regional Harmonisation Initiatives (RHIs) that wish to participate. RHIs may represent their constituents and promote harmonisation in the whole region. Observers will be considered on a case-by-case basis and subject to endorsement by the Management Committee (MC) and currently include the World Health Organization (WHO) and the European Directorate for the Quality of Medicines & HealthCare (EDQM). There will not be any differences in expectations and level of participation between members and observers. To ensure the most effective discussion, each regulatory authority or organisation should be represented by senior staff from the organisation preferably with direct line responsibility for oversight and management of regulatory operations, product-related decisions, and policy issues. Membership in

[1] A generic pharmaceutical product is generally defined as a pharmaceutical product that, in comparison with a reference product, is pharmaceutically equivalent to the reference product (i.e. the same amount of the same active substance in the same dosage form), and is equivalent to the reference product in terms of safety, efficacy, and quality. It is recognised that individual Regulatory Authorities (RAs) or Groups of RAs may have regulatory definitions for a generic pharmaceutical product that differ from the above.

IPRP is inclusive; prospective eligible parties can submit an expression of interest to the IPRP Secretariat for consideration by the MC.

External experts may be consulted on an ad-hoc basis on topics for consideration by the MC or a Working Group (WG). A member or observer of the IPRP requesting permission for an external expert to attend an MC or WG meeting shall provide a written request to the IPRP Secretariat at least 30 days before the meeting, asking for the MC to endorse their attendance.

## GOVERNANCE AND MANAGEMENT[2]

### A. Management Committee

The decision-making body of the IPRP is the Management Committee (MC). The purpose of the MC is to provide strategic direction; identify and prioritise challenges to be addressed and collaborative activities; allocate resources in support of advancing the IPRP's goals and objectives; exercise oversight of the working groups and to determine the implementation process and monitor the work plan(s).

The MC is comprised of up to three (3) official representatives from each participating member and observer. A member or observer may appoint additional MC representatives who may attend face-to-face meetings as space permits. All MC representatives should be included in correspondences to the MC.

The presence of at least 50% of the members plus one is required to constitute a quorum. A quorum is required to be present for the IPRP MC to adopt decisions. While the MC may take some minor decisions at virtual meetings, including with respect to the organisation of meetings, significant decisions including the approval of major documents such as the Terms of Reference or Standard Operating Procedures should generally be made at face-to-face meetings. All members and observers are committed to the goals and objectives of the IPRP and to making best efforts to reach consensus. The members and observers of the MC will reach decisions by consensus (not voting) on matters related to the operations of the organisation.

#### i. MC Member and Observer Responsibilities

The responsibilities of MC members and observers include, but are not limited to, the following:

- actively participate in meetings and web or teleconferences and work via email, as necessary in order to most efficiently conduct the work of the MC;
- communicate and interact with other members and observers of the MC in order to provide input based upon regulatory experience in all relevant aspects of pharmaceutical regulation; and
- fulfil commitments made to other MC members and observers in follow up to MC meetings and discussions.

[2] For a graphical overview on the governance structure refer to Annex 1.

### ii. MC Chair

The Chair will be appointed by the MC members and observers and will serve in the role for a term of 1 year which may be renewed up to three times. Working closely with the MC members and observers, the Chair will be responsible for developing a longer-term plan of discussion topics, drafting agendas for the meetings and web or teleconferences, facilitating and conducting the face-to-face meetings, periodic web or teleconferences, and leading the group in making progress on topics or sun-setting those topics in which progress cannot be made or are no longer viewed as a priority. The Chair will work closely with the Secretariat.

A Vice-Chair will also be appointed from the MC members and observers, for the same renewable term length, and will assist the Chair, sharing the management workload and helping maintain progress on the work undertaken by the MC.

## B. Working Groups

The MC will establish Working Groups (WGs) to undertake certain work on identified/selected topics or projects. A Chair or two Co-Chairs will be appointed from the members or observers of the MC. These WGs shall have clearly documented mandates and specific activities as approved by the MC. A WG should normally be disbanded upon completion of its mandate or at the discretion of the MC.

The Chair(s) of the WGs are responsible for keeping the contact information of their group members and observers up-to-date and for initiating collaboration with similar WGs.

### i. Working Group Mandate and Working Group Work Plan

The mandate and work plan of a WG is reviewed and endorsed by the MC. The mandate will be developed following the initial establishment of the WG and will include a clear statement of the WG's remit and date of endorsement by the MC. The mandate will also include general considerations, objectives, scope of the activities, and participating members and observers. The Mandate and Work Plan should be re-evaluated and updated as needed at least once a year ahead of the second face-to-face meeting of the MC in that year. The work plan must include the following information:

- Statement of the proposed work product(s) to be delivered
- Anticipated milestones and timeline for completion
- Topic 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 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.

### ii. Participation on Working Groups

Participation in the work of IPRP is open to all members and observers and is voluntary. IPRP members and observers are not required to participate on all WGs and may "opt-out" from some activities as the IPRP operates on a voluntary basis.[3]

Chairs of the WGs are expected to keep the MC updated on a periodic basis, or upon request. Nomination of the WG Chair or Co-Chairs by the WG members and observers must be endorsed by the MC. Appointment is for 2 years, renewable at the discretion of the MC.

### C. Secretariat

The IPRP will be supported by the Secretariat whose function will be to act as an administrative point of contact, and will facilitate and coordinate work by undertaking such tasks as disseminating information, coordinating meetings and maintaining a repository of documents and tools of communication (such as the website). The scope of activities of the Secretariat will depend on the voluntary financial contributions of the MC members. For a full list of the Secretariat responsibilities see Annex 2.

Following establishment of the IPRP initiative, any pre-existing content from the predecessor IPRF and IGDRP initiatives will be handed over to the newly established Secretariat.

## COLLABORATION MECHANISMS

### A. Project Proposals

All members and observers may propose projects and work items to the MC for consideration. These recommendations can come through formal submissions in writing, or through presentation at a meeting of the MC.

### B. Networks

For the ongoing exchange and sharing of information, the IPRP may establish networks (e.g., a discussion forum). These networks may be formed by key focal points from each of the members and observers.

### C. External Collaboration

The IPRP may establish relationships with existing international initiatives with a view to promoting synergy and sharing of information. The IPRP will also remain open to considering engagement with others that might contribute to IPRP work.

[3]While products of the IPRP will reflect the views of the subject matter experts who participated in those working groups, products may not reflect the view of all IPRP members and observers and should not be construed to represent the official views of any given regulatory authority or organisation participating in IPRP.

When participating in international events or meetings not specifically on behalf of the IPRP, IPRP members and observers shall make clear that their views expressed are their own views and not those of the IPRP.

When an IPRP member or observer accepts an invitation to represent the IPRP at an international or other forum, the IPRP Secretariat should be informed prior to the event. It is the responsibility of the member or observer to ensure that the views expressed are those of the IPRP. Documents and presentations delivered by a member or observer on behalf of the IPRP should be submitted to the MC for tacit approval prior to use. In instances where a WG will present on the ongoing work of the WG, the slides should be submitted to the Chair/Co-Chairs for approval and shared with the entire membership of the WG for any concern ahead of the presentation.

## MEETINGS

### A. Management Committee

The MC will meet face-to-face twice a year. These meetings will be considered to take place in conjunction with the meetings of the ICH. In addition to face-to-face meetings, the MC will have periodic and ad hoc web or teleconferences.

### B. Working Groups

WGs may meet face-to-face and through web or teleconferences, and exchange information through e-mail. Any face-to-face meeting of a WG will be subject to decision by the MC. The MC will assess the need for a WG meeting based on the proposed meeting agenda and the expected deliverables. 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. A WG may receive standing approval to meet face-to-face on a regular schedule for a defined period. WG meetings may take place in conjunction with the MC meeting or separately depending operational considerations (e.g., the availability of space and the needs of the WG).

During each meeting of the MC, a report on the progress of the WG should be provided and a request for approval of the work plan should be submitted to the MC. The Chair(s) of each WG will be invited to join the MC meeting to provide this report either in person or remotely (by web or teleconference).

## COMMUNICATIONS

The IPRP website will be the primary tool for external communications (e.g., to publish papers, issue press releases, and provide other relevant information).

In general, a communication (e.g., a Public Statement) will be provided following each meeting (based on consensus of the members and observers) describing at a high level recent issues for discussion and accomplishments of the MC. This communication will be provided through the external website.

Considering the sensitivity of the information that may be exchanged, members and observers may be required to treat some of the information exchanged as confidential.

Subject to MC approval, the IPRP may decide to hold a public meeting to provide an opportunity to present on relevant updates and for open discussions on possible work items, planning strategies or other issues. The MC may also solicit the input of stakeholders by other mechanisms (public consultation, call for input, etc.).

Information shared during IPRP activities should be considered non-public information and handled in confidence by IPRP members, observers and external experts, unless otherwise indicated. All external communication not already publicly available or pre-approved must be authorised by the MC.

## PUBLICATIONS

The author(s) of a paper or report will have ownership of the document and must acknowledge contributions by the IPRP members and observers. Draft papers or reports should be treated in confidence and shall not be disclosed externally by members or observers until publication occurs. The publication of papers or reports on IPRP work activities in other media (e.g. scientific journals) must be endorsed by the MC following circulation and agreement on the content by the members and observers. The publication in other media should embrace "open access" (e.g., would not require membership to a scientific journal to access) and not prevent the ability to also publish these papers or reports on the IPRP website. Any restrictions to publishing on the IPRP website shall be informed to the MC for advice when nominating the medium or as soon as it is known.

### A. Website

The IPRP website will be developed and supported by the Secretariat. An internal document sharing platform will also be established in addition to an external website to publish papers, issue press releases, and provide other relevant information.

### B. Language

The working language of the IPRP is English. Meetings will be conducted in English and documents will be distributed in English. It is each member's and observer's responsibility to translate any documents into additional languages as needed.

## FUNDING

Activities of IPRP will be financed through contributions by its members through funding mechanisms that are consistent with the laws regulating the activities of each member. There should be regular monitoring to ensure that the funding corresponds to the resources required for the services provided and adjustments should be made, if needed.

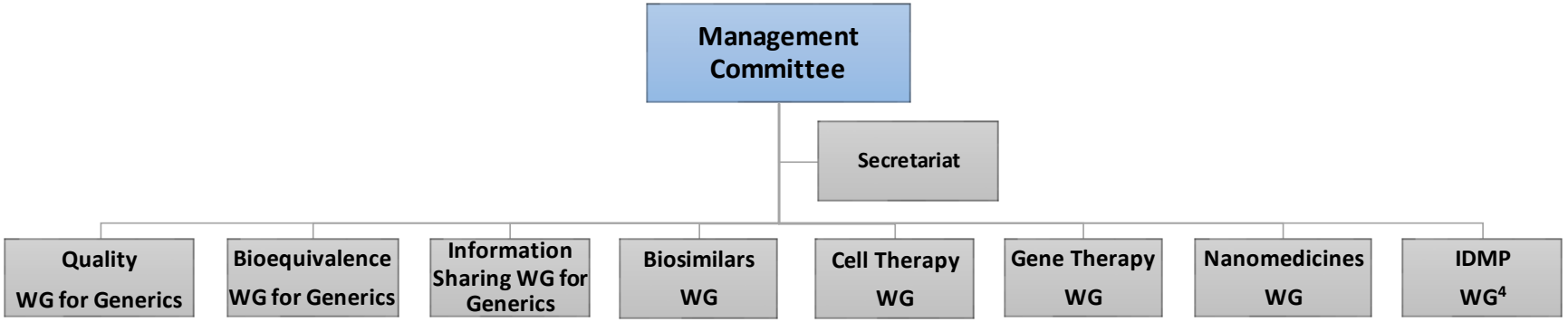
Members, observers and external experts are responsible for all costs associated with their own travel to and from the meeting site and their accommodations.

## REVIEW OF TERMS OF REFERENCE

The Terms of Reference will be reviewed and approved every two years by the MC or as needed following recommendations from the MC.

The Secretariat will be responsible for coordinating the review of the Terms of Reference.

# Annex 1 - Governance Structure of IPRP




[4]Identification of Medicinal Products (IDMP)

# Annex 2 - Secretariat Responsibilities

| | IPRP Secretariat |
|---|---|
| **General Administration** | • Support the day-to-day running of the IPRP Secretariat office;<br>• Provide office support including archiving and maintenance of documents and records, support for TCs, virtual working areas for WGs/MC; |
| **Financial Administration** | • Support financial administration;<br>• Manage invoices;<br>• Draft Secretariat budgets and closing reports (TBD); |
| **Logistic support of TC/Meetings** | • Support hosting of biannual meetings;<br>• Provide assistance to participants in IPRP meetings, e.g., invitation letters;<br>• Provide on-site Secretariat services for meetings;<br>• Organise the dates of TC/meetings; |
| **Support of MC decisions** | • Support decision-making of the MC (e.g., provide background/meeting materials, collect documents), to enable them to fulfill their functions in an efficient and timely manner;<br>• Develop Agendas/Reports of TC and meetings, circulate for comment and make revisions for finalisation;<br>• Collect and manage requests according to procedures, e.g., WG nominations;<br>• Ensure relevant information is made available to the MC to inform them of WG progress; |
| **Support of Working Groups** | • Provide technical support to WGs;<br>• Follow up on MC decisions, provide advice on procedural and other matters;<br>• Liaise with WG Chairs to ensure the smooth functioning of WGs, the meeting of deliverables in accordance with agreed timelines, and the appropriate flow of information to MC regarding WG activities (work plans, reports, etc);<br>• Maintaining MC and WG membership lists and contact information; |
| **Manage Procedures** | • Manage operations in line with established procedures and continually seek opportunities for enhancement;<br>• Ensure compliance with procedures by the Secretariat, MC, & WGs; |
| **Support strategy** | • Develop IPRP Work Plans (strategic content within work plans TBC my MC);<br>• Develop templates for IPRP brand and documents (e.g., outputs, workplans, presentation decks) |
| **Ensure communication with stakeholders** | • Ensure the website is kept up-to-date (e.g., news, document publication, reports) and user-friendly;<br>• Ensure the official documents (reflection papers, reports, etc) are publication-ready (e.g., formatting, consistency);<br>• Provide support for communication with stakeholders, e.g., respond to emails and phone calls, issue letters;<br>• Coordination of bi-annual symposium. |