Terms of Reference

International Pharmaceutical Regulators Forum (IPRF)

1 Purpose

The Regulators Forum was originally created as a safe harbor for discussion and promotion of harmonization among regulatory authorities and Regional Harmonization Initiatives (RHIs), hereafter referred to as “members”. The Regulators Forum has evolved to the point of needing a more formal structure and the following Terms of Reference were created to provide for future activities.

The purpose of the International Pharmaceutical Regulators Forum (IPRF) is to create an environment for members to exchange of information on issues of mutual concern and regulatory cooperation. This dedicated venue will maximize potential efficiencies in addressing the increasingly complex global context of medicines regulation, will facilitate the implementation of ICH and other internationally harmonized technical guidelines for pharmaceuticals for human use and will contribute to the coordination of a range of international efforts related to regulation of medicinal products for human use.

2 Goals

The IPRF provides members a unique opportunity to leverage the expert scientific knowledge, regulatory and operational experience, on-going technical harmonization work, and information access of the other members. The first goal is to enable all members to identify new approaches and specific best practices, and develop smart strategies for dealing with the challenges of a rapidly evolving globalized pharmaceutical industry. The second goal is to provide a global overview of the different regulatory developments at national and international level and enable open sharing of information and ideas among regulatory leaders with hands-on operational responsibilities. This information sharing will allow the members to discuss the details of the issues and the necessary actions with the experts at their organizations, following the IPRF meetings. The third goal is to support international regulatory cooperation in areas which are not covered by existing initiatives.

3 Objectives

Objectives of the IPRF include the following:

- Practical and operational information-sharing on high priority regulatory issues;
- Support implementation of ICH and other internationally harmonized technical guidelines for medicinal products for human use;
- Regulatory cooperation, including work sharing, on identified topics which are not duplicative of existing processes or organizations.

- Open discussion and the sharing of best practices among the members;
- To identify existing synergies and commonalities with a view to develop common approaches;
- In the context of a particular issue, identification of common need for development of
  - Better regulatory strategies,
  - Better information on specific issues or
  - Better training, e.g., for regulatory staff, to address specific issues;
- Identification of need for harmonization or convergence in specific areas (to improve regulatory operations efficiency and effectiveness);
- Propose identified topics, not falling in the remit of the IPRF, to appropriate existing process or venues (e.g. to ICH, PIC/S, APEC, PANDRH, WHO, etc.);

4 Scope of Activities

The IPRF will engage in regular discussions related to the objectives outlined above. The products covered are medicinal products for human use ("Pharmaceuticals"). Sample discussion topics might include scientific and technical requirements related to efficacy, safety or quality for drug marketing (registration), regulatory oversight of clinical trials and manufacturing sites, electronic data strategies ; and other issues of emerging concern.

5 Governance/Management

A. Membership

The membership of the IPRF would be comprised of representatives from regulatory authorities, Regional Harmonization Initiatives (RHIs) that wish to participate, and WHO as observer. RHIs may represent their constituents in the Regulators Forum and promote harmonization in the whole region. To ensure the most effective discussion, each regulatory authority would be represented by senior staff from the government organization or agency preferably with direct line responsibility for oversight and management of regulatory operations, product-related decisions, and policy issues.

B. Member Responsibilities

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

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

C. Chair

The chair will be appointed by the members of the IPRF and will serve in the role for a term of 1 year which may be renewed up to three times. Working closely with the IPRF members, the chair will be responsible for developing a draft longer-term plan of discussion topics, drafting agendas for each meeting, facilitating and conducting the face-to-face meetings, periodic teleconferences, and/or videoconferences, and leading the group in making progress on topics or sunsetting those topics in which progress cannot be made. The chair will work closely with the Secretariat.

A co-chair will also be appointed from the membership, 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 IPRF.

D. Secretariat

The IPRF 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 web.

The responsibilities of the secretariat may include the following:

- drafting meeting and teleconference minutes;
- circulating minutes for comment, revision and circulating final version;
- scheduling periodic teleconferences;
- maintaining membership list and contact information;
- acting as point of contact for information sharing among members;
- serving as point of contact for external communications;
- creating and maintaining a repository for documents;
- developing and maintaining website;
- coordinating meeting logistics;
- distributing background materials and other documents to members prior to meetings and teleconferences;
- coordinating the review of the Terms of Reference.

The scope of activities of the secretariat will depend on the voluntary financial contributions of the members. In an initial phase, the activities of the secretariat will be ensured by the members of the IPRF.

6 Collaboration Mechanisms

A. Working Groups

The IPRF will bring forward the work that has been initiated by the Regulators Forum and may establish additional working groups to undertake certain work on identified/selected topics or projects, chaired by a member of the IPRF. These working groups shall have clearly documented mandates and specific activities (for example: prospective cellular therapies harmonization, or sharing of information on GCPs or GMPs among the members). Participation in the groups is open to all members and is voluntary. Chairs of the groups are expected to keep the IPRF updated on a periodic basis, or upon request.

B. Project Proposals

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

C. Networks

For the ongoing exchange and sharing of information, the IPRF may establish networks. These networks may be formed by key focal points from each of the members.

D. Liaison

The IPRF may establish relationships with existing initiatives with a view to promoting synergy and sharing of information.

7 Meetings

The IPRF will initially meet face-to-face at least twice a year. For practical reasons, these meetings will take place in conjunction with ICH meetings. In addition to face-to-face meetings the IPRF will have periodic and ad hoc web/teleconferences.

In general, the IPRF will provide public communication following each meeting (based on consensus of the members) describing at a high-level recent issues for discussion and accomplishments of the Forum. Considering the sensitivity of the information that may be exchanged , members may be required to treat some of the information exchanged as confidential.

All members are committed to the goals and objectives of the IPRF and to making best efforts to reach consensus. All work within the IPRF is done on a voluntary basis.

8 Communications

In conjunction with the IPRF face-to-face meetings, there may be a public meeting, to which all interested stakeholders are welcome. This public meeting will provide an opportunity for open discussions on possible work items, planning strategies or other issues. The IPRF may also solicit the input of stakeholders by other mechanisms (Public consultation, call for input, etc.).

A. Website

A web hosting site for document sharing and information postings will be developed and supported by the Secretariat.

B. Language

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

9 Support of activities

Members and stakeholders are responsible for their own travel to and from the meeting site and their accommodations.

In an initial phase, the Secretariat will be hosted by a one of the members. Members may also contribute to the IPRF by hosting meetings or providing staff.

10 Review of Terms of Reference

The Terms of Reference will be reviewed and approved annually by the IPRF or when necessary.