

IMDRF International Medical
Device Regulators Forum

Final Document

Title: IMDRF Terms of Reference
Authoring Group: IMDRF Management Committee
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A handwritten signature in black ink, appearing to read 'Yuan Lin', is located below the text 'IMDRF Chair'.

YUAN Lin, IMDRF Chair

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International Medical Device Regulators Forum

Terms of Reference

I. Introduction

A. Mission

The mission of the International Medical Device Regulators Forum (IMDRF) is to strategically accelerate international medical device regulatory convergence to promote an efficient and effective regulatory model for medical devices that is responsive to emerging challenges in the sector while protecting and maximizing public health and safety.

B. Goals

IMDRF is established to address the common public health regulatory challenges to convergence due to the globalization of medical device production and the emergence of new technologies. IMDRF provides the structure where the strategic decisions and operational mandates are made by public health-missioned medical device regulators, based on appropriate, equitable and transparent input from stakeholders.

C. Objectives

The objectives underpinning the goals of IMDRF are to:

- Accelerate international medical device regulatory convergence
- Support innovation and timely access to safe and effective medical devices globally
- Promote open discussion and the sharing of best practices among regulatory authorities responsible for medical device regulation
- Facilitate frequent exchange of policy and regulatory information of common interest to regulatory authorities
- Provide opportunities to identify commonalities and develop approaches to overcome unnecessary regulatory barriers
- Promote prospective convergence in areas of advanced and innovative technologies
- Enhance communication, information sharing and scientific exchange among regulators and a broad range of stakeholders
- Establish develop dialogue with other relevant organizations.

¹ "Regulatory convergence" (hereinafter "convergence") is meant to represent a voluntary process whereby the regulatory requirements and approaches across countries and regions become more similar or aligned over time as a result of the adoption of the same technical documents, standards and scientific principles (harmonization) and similar regulatory practices and procedures. The process of convergence represents an important form of regulatory cooperation which in turn makes possible additional, enhanced forms of cooperation and collaboration between regulatory authorities.

D. Scope of Activities

IMDRF will pursue its goals by defining, implementing and evaluating strategic priorities so that objectives are met in an efficient and effective manner.

IMDRF will facilitate the identification, design and implementation of activities that best meet the needs of the participants with regard to convergence. The scope of activities will include:

- Working with IMDRF participants to develop a prioritized annual work plan of activities, taking into consideration the regulatory requirements and constraints that govern each regulatory authority (with respect to the sovereignty of each regulatory authority)
- Undertaking initiatives, projects and issues of common interest and concern to regulatory authorities considering, when appropriate, the input from stakeholders
- Enhancing the knowledge about regulated medical devices through information sharing
- Facilitating mechanisms for the sharing and use of relevant information and the exchange of scientific expertise
- Complementing the goals and objectives of the Global Harmonization Task Force (GHTF) by providing a structured approach to implementing, revising and maintaining GHTF documents and, if required, develop other guidance documents to achieve convergence across global medical device regulatory activities.

IMDRF activities and initiatives (work products) that further convergence may fall into three categories:

1. governance documents (created to address procedural and decision making matters of the IMDRF);
2. technical documents (created to address technical matters relating to the regulation of medical devices); and,
3. information documents (created to provide clarification, status, and/or needed information about a particular work item where public consultation is not needed).

II. Governance Structure

A. Organization Structure

See Appendix A

B. Management Committee

The Management Committee (MC) makes decisions on behalf of the IMDRF; provides strategic direction; identifies and prioritizes regulatory challenges to be addressed; determines the implementation process and monitors the work plan; and authorizes resources in support of advancing IMDRF's goals and objectives.

Membership

MC membership is comprised of representatives from the medical device regulatory authorities of Australia, Brazil, Canada, China, the European Union, Japan, the Russian Federation, Singapore, South Korea and the United States. There are two representatives per country delegation and four representatives for the European Union delegation. This allotment does not include the Chair of the MC, who will be considered separate from the chairing country/region delegation. Each delegation shall have equal voice in decisions regarding IMDRF.

An alternate may be designated by a delegation to replace one of its members in rare instances where the member is unable to participate in a meeting. The alternate should be fully knowledgeable on IMDRF matters and have the authority to speak on behalf of the member regulatory authority.

MC membership will be reviewed when required. The admission of new member organizations is a MC decision. If it is considered, over time, that the expansion to other regulatory authorities contributes to the contemporary and foreseeable public health-missioned responsibilities, membership can be expanded, with the unanimous consent of the MC.

Chair

The Chair of the MC will lead activities of IMDRF, including conducting all the MC meetings. The Chair must be from a regulatory authority and will rotate annually among the members of the MC in conjunction with the Secretariat function.

Secretariat

The Secretariat is responsible for facilitating and coordinating the work of IMDRF and the MC Chair by undertaking such tasks as disseminating information, coordinating MC meetings and maintaining a repository of documents and the tools of communication such as the web. The Secretariat corresponds to the IMDRF Chairpersonship and rotates annually.

Official Observers

The MC may designate a limited number of Official Observers to the MC from the World Health Organization and other regulatory authorities on the basis of perceived contribution or value to IMDRF. Official Observers do not participate in the decision making process. Official Observers must be approved by the unanimous consent of the MC through the process described in the IMDRF Standard Operating Procedures (SOP) and, as with Members, need to be fully knowledgeable on IMDRF matters.

Invited Observers

The MC may invite an organization to attend a MC meeting on the basis of perceived contribution or value to IMDRF. Invited Observers do not participate in the decision making process, and attend only 'Open' portions of the MC meetings at the invitation of the Chair.

Regional Harmonization Initiatives

IMDRF seeks to maintain working relationships with other international entities or regional organizations called "Regional Harmonization Initiatives (RHIs)" that have a mutual interest in medical device regulatory activities that are directly related to the common goals of fostering global convergence, leveraging resources and making available safe and effective medical devices globally.

An RHI participate in a MC meeting by invitation of the MC Chair. RHIs do not participate in the decision making process. RHIs must be approved by the unanimous consent of the MC through the process described in IMDRF SOP

An RHI may nominate up to two (2) regulators to attend the MC meetings. The regulators representing the RHI may not already be a member of the MC or Official Observer for their specific country or jurisdiction. The regulators representing the RHI must consistently represent the RHI for a period of 12 -24 months and then optimally rotate to a different regulatory authority or jurisdiction per a procedure developed by the RHI. The regulators representing the RHI must agree to keep all non-public discussions of the IMDRF MC confidential.

Subcommittees Creation/Termination/Renewal

Subcommittees (SC) are groups that are established by the MC to draft policy documents that are created to address governance, procedural and decision making matters of the IMDRF, or other matters that are not appropriate for a Working Group. SCs may cover such issues as training, communication and document maintenance including GHTF documents. The MC may redefine the mandate, charge new tasks, appoint/reappoint the SC Chair, create a new or terminate an existing SC.

Participation on Working Groups

A Working Group (WG) will be constituted in terms of size and representation as determined by the MC. WGs responsible for developing technical documents, would generally involve the participation of stakeholders that have significant involvement in the development, manufacture or use of medical devices including, but not limited to, regulated industry, international entities and associations, academia, patient and consumer groups, medical professionals, and other regulatory authorities.

WGs responsible for developing technical documents that involve the exchange of sensitive or confidential information or involve the specific practices or procedures of the regulatory authorities, would be comprised exclusively of representatives from regulatory authority members. When WGs of regulatory authorities only are formed, the MC will provide a clear and transparent justification for the limitation of membership on these WGs.

Nomination of Members, including the WG Chair, must be endorsed by the MC. If a WG is to include stakeholders, these stakeholders should be nominated/selected based upon their expertise in the specific subject matter and their ability to actively contribute to the activities of the WG.

III. Work Products

Regulators and stakeholders may propose, in writing, projects and work items to the MC for their consideration. These proposals can come through formal submissions to the MC. The MC is responsible for evaluating and deciding on all proposals and their priorities, and will instruct the development of the work plan to include the agreed upon projects. The MC may limit the number of projects undertaken based on available resources, feasibility and member interest.

Document Development

IMDRF undertakes initiatives and projects to address issues of common interest and concern to regulatory authorities. The key work products produced from the agreed work plan priorities consist of governance documents and technical documents.

The governance documents are consensus driven documents and are applicable to all MC members once approved by the MC.

Technical documents relating to the regulation of medical devices will be developed to reflect the regulators' efforts to achieve convergence of regulatory practices across a specific area.

Implementation Initiatives

MC member organizations may, in exceptional cases, decide to opt-out of or delay involvement in implementation initiatives or involvement in the development of technical documents. This could, for example, occur due to constraints presented by existing regulatory systems, decisions to delay involvement until the conclusion of a pilot or because the initiative addresses the concerns of a subset of MC members.

IV. Meetings

IMDRF will initially meet face-to-face biannually dependent on the Chair/Secretariat, who is responsible for hosting the meetings. The biannual meetings will be conducted in plenary with three successive sessions:

- a public IMDRF meeting with a structured dialogue between the MC and stakeholders to provide input to planning strategies and suggestions for work items, exchange information with the MC, and discuss work products;
- MC caucus with reports from SCs and WGs (this may include closed and open sessions); and
- a MC caucus, with adoption of the MC meeting's report at the close.

In addition to face-to-face meetings the MC will have periodic web/teleconferences. There will also be periodic web/teleconferences with SCs and WGs in order to provide appropriate follow-up on work items.

Conduct of MC Meetings

MC Meetings are generally attended by the Chair, MC members, Secretariat, Official Observers, Invited Observers and RHIs. Where a discussion item is designated 'closed', only the Chair, MC members, Secretariat and Official Observers may attend. RHIs may attend in portions of the 'closed' session by invitation of the MC Chair. Discussion items may be designated as 'closed' at the discretion of the Chair. The MC may invite an expert to a certain session of the MC meeting by meeting basis.

Confidentiality

Discussions and outcomes of the closed MC meetings as well as communications amongst MC members and Official Observers will be kept confidential unless the MC members unanimously agree to make some or all of the discussions/communications public.

Public IMDRF meetings

In conjunction with the MC's biannual face-to-face meetings, there will usually be a public IMDRF 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.

Decision Making

All parties are committed to the goals and objectives of IMDRF and to making best efforts

to reach consensus. The MC will reach decisions by consensus and not voting. However in exceptional cases, MC member organizations may opt-out of decisions on implementation initiatives. The MC will handle other exceptional instances where full consensus cannot be reached on a case by case basis.

V. Communication

Website

A web hosting site for document sharing and information postings will be supported by IMDRF through a contract held by an MC member. The member would provide the webmaster services and would work with the Secretariat to maintain current postings to the web site or other shared location.

Outcome Statement

The MC will issue an outcome statement of each biannual face-to-face meeting. The outcome statement will include an overview of the meeting as well as the MC's decisions made during the meeting.

Logo

The IMDRF logo is to be used to brand activities and documents approved by the MC.

Language

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

VI. Funding

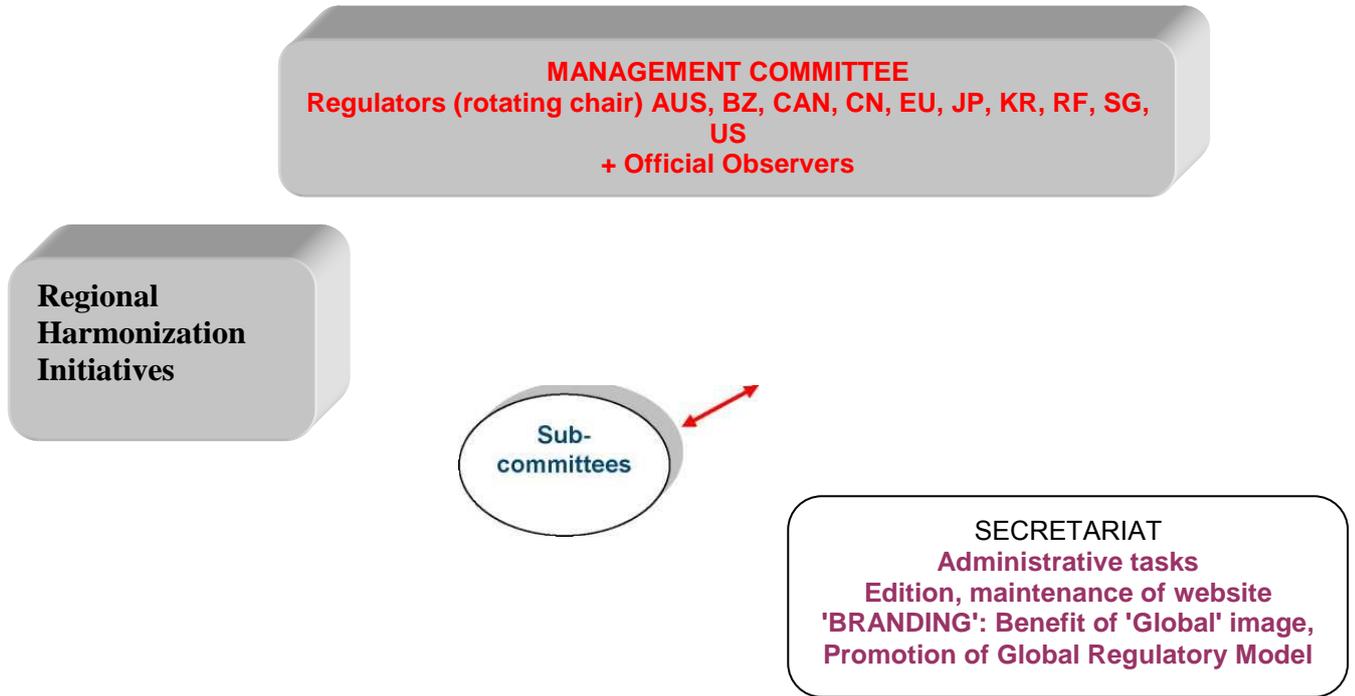
Members, Official Observers, Invited Observers, RHIs and stakeholders are responsible for their own travel to and from the meeting site and their accommodations.

VII. Review of Terms of Reference

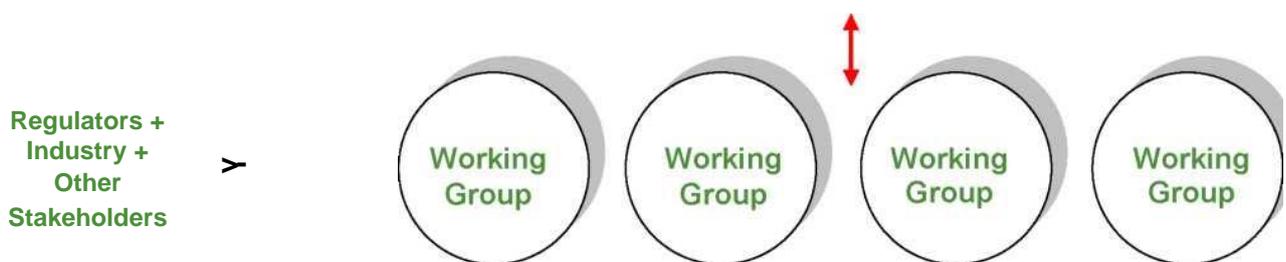
The Terms of Reference will be reviewed annually, at the occasion of the rotation of the Chair, to ensure they reflect the current goals and objectives of IMDRF.

Appendix A - IMDRF Organization

INTERNATIONAL MEDICAL DEVICE REGULATORS FORUM



MANAGEMENT LEVEL *Decision Making, strategic direction, work plan monitoring*



OPERATIONAL LEVEL *Technical document development*