International Generic Drug Regulators Programme

Terms of Reference

(Updated: 30 June 2016)

I. Introduction

A. Mission

To promote collaboration and regulatory convergence[1] in the area of generic drug regulation in order to strengthen the ability of health authorities to meet their respective mandates.

B. Goal

To facilitate efficient use of resources, timely authorization and availability of safe, effective and high quality generic drug products.

C. Objectives

- Create conditions which enable greater inter-agency collaboration.
- Foster peer discussion to bring a broader set of perspectives to bear on scientific and regulatory issues.
- Promote greater alignment of regulatory approaches and technical requirements based on international standards and best practices
- Enhance and better coordinate the international regulatory oversight of generic drug products.
- Promote the adoption of modern science- and risk-based approaches to the development and regulation of generic drug products.
- Promote increased efficiency, consistency and predictability in regulatory assessments and decisions.
- Enhance communication, information-sharing, and scientific exchange leading to greater work-sharing and potential mutual reliance on regulatory assessments.
- Promote transparency and clarity of regulatory and procedural requirements.
- Enhance the development of human resources and competencies.
- Reduce regulatory burden without compromising the safety, efficacy, or quality of generic drug products.

D. Scope of Activities

The IGDRP will undertake activities that best meet the needs of the participants in the area of generic drug regulation. A generic drug product is generally defined as a drug product that in comparison with a reference product:

a. is pharmaceutically equivalent to the reference product (i.e., the same amount of the same active substance in the same dosage form), and

[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 guidance documents, standards and scientific principles (harmonisation) and similar regulatory practices, procedures and definitions of key elements. 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.

b. is equivalent to the reference product in terms of safety, efficacy, and quality

It is recognised that individual IGDRP members may have regulatory definitions for a generic drug product that differ from the above.

This initiative does not include biosimilar/subsequent-entry biologicals.

The IGDRP will pursue its goals by adopting a pragmatic step wise approach to identifying, evaluating and implementing strategic priorities so that objectives are met in an efficient and effective manner.

The following key principles will guide the operation of the IGDRP:

- Participating regulatory authorities may "opt-out" from any work plan activities. This could, for example, occur due to constraints presented by existing regulatory systems or because the initiative addresses the concerns of a subset of Steering Committee members.
- Activities will complement and not duplicate work undertaken elsewhere.

II. Operating Arrangements

A. IGDRP membership

IGDRP members include Steering Committee (SC) members as well as Working Groups (WG) members.

Individuals on the SC and on the WGs should have the requisite expertise, experience and ability to represent their regulatory authority/network of authorities and contribute to progressing the programme, actively participate in meetings, work via email, teleconferences, and in-person meetings, as necessary in order to most efficiently conduct work of the IGDRP.

In response to a request from a regulatory authority to become a new IGDRP member, the regulatory authority making the request can participate during IGDRP discussions as an Observer for an interim period, until such time the request can be fully considered by the Steering Committee.

A list of IGDRP members is appended to this document (Appendix A)

B. Steering Committee (SC)

The SC:

- makes decisions on behalf of the IGDRP;
- provides strategic direction;
- identifies and prioritises challenges to be addressed and collaborative activities;
- determines the implementation process and monitors the work plan(s); and
- authorises resources in support of advancing the IGDRP's goals and objectives.

The SC comprises one representative from each participating member and one observer each from the World Health Organization (WHO) and the European Directorate for the Quality of Medicines (EDQM).

For consistency and continuity reasons it is recommended that an alternate be nominated by each participating member. Both the SC member and alternate may participate at the meetings of the IGDRP. The alternate should be fully knowledgeable on IGDRP matters and have the authority to speak on behalf of the SC member.

Each SC member shall have equal voice in decisions regarding IGDRP.

a. SC Decision Making

All parties are committed to the goals and objectives of the IGDRP and to making best efforts to reach consensus. The SC will reach decisions by consensus (not voting) on matters related to the operation of the programme. However, SC members may opt-out of participation of specific working group or other work plan activities.

b. Chair and Co-Chair

The Chair will rotate at each meeting. The Chair will be assisted in the preparation and chairing of face to face meetings by a Co-Chair, who will also be from the SC. The Chair will serve as Co-Chair for the meeting following his/her tenure as Chair, thereby providing continuity of operation. The Chair, or his/her designate, will be responsible for the organisation of the meeting and for preparing a record of discussion.

c. Observers

The SC may designate observers to the SC from regulatory authorities on the basis of perceived contribution or value to the discussions. Observers are expected to attend SC meetings, but do not participate in the decision making process. Observers must be approved by the unanimous consent of the SC and, as with SC members, need to be fully knowledgeable on IGDRP matters.

C. Working Groups (WGs)

a. Creation/Termination/Renewal

WGs may be established by the SC to undertake work on specific issues and activities identified in the work plan. Upon completion of its specific mandate, the WG shall be terminated.

b. WG Mandate and WG Work Plan

The mandate of the WG is defined and agreed by the SC prior to the establishment of the WG. The mandate includes at least the following information:

- Goals and Objectives
- Participating regulatory authorities and organisations (annexed)
- High-level work plan (as defined in an IGDRP concept note template)

The high-level work plan is used as a basis for a more detailed work plan describing the activities foreseen within the next six to twelve months. This work plan is presented to the SC for agreement as a part of the report of the WG to the SC.

c. Participation on Working Groups

WGs will be constituted in terms of size and representation as determined by the SC.

Nomination of the WG Chair or Co-Chairs by the Working Group members must be endorsed by the SC. Appointment is for 3 years, renewable at the discretion of the SC.

Individual members should be nominated by the respective IGDRP jurisdictions.

If a WG is to include external experts, the experts 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.

D. External Experts

External experts may be consulted on topics for consideration by the SC. Such experts may also be invited to participate in working groups, depending on perceived value and with the endorsement of the SC.

E. Secretariat

The Secretariat is responsible for facilitating and coordinating the work of the IGDRP and the SC by undertaking such tasks as disseminating information, coordinating SC meetings, and maintaining a repository of documents and the tools of communication (e.g. the IGDRP website). The Secretariat can also provide similar support to WGs when appropriate.

The Therapeutic Goods Administration of Australia will act as an Interim Secretariat and establish and host a website for the programme for two years. The provision of these services and functions, including how the shared services will be resourced, will be considered during this period

III. Meetings

A. Steering Committee

The SC will normally meet face-to-face twice a year.

The SC will decide on location of meetings based on expression of interest.

The host will chair the meeting. The date and location of meetings will be determined by the SC. The SC may also hold ad hoc teleconferences.

B. Working Groups

The WGs will mainly work remotely through telephone or web-conferences. The WGs will meet twice a year in conjunction with SC. These meetings can be organised in conjunction with the SC meeting or separately in case it can be linked to, for example, an experts conference, where most of the work group members may be participating.

IV. Treatment of information and Communication

A. Language

The working language of the initiative is English. It is each region's responsibility to translate any documents into additional languages as needed.

B. Treatment of information

Information shared during IGDRP activities should be considered non-public information and handled in confidence by IGDRP members and observers, unless this is otherwise indicated.

All documents and information will be shared amongst IGDRP members through a secure platform.

Read-only or restricted access can be granted upon request to other regulatory authorities not actively participating in the IGDRP.

C. External communication

All external communication not already otherwise publicly available must be authorised by the SC.

Information on the IGDRP will be provided to external interested parties/stakeholders through the website (IGDRP.com).

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

D. Participation in international or other fora

When participating in international or other fora not specifically on behalf of the IGDRP, IGDRP members shall make clear that their views expressed are their own views and not those of the IGDRP.

In case an IGDRP member participates in international or other fora and represents the IGDRP, he/she shall make sure that the views expressed are those of the IGDRP. The IGDRP Secretariat should be informed prior to the event.

The IGDRP member will be asked to report back to the IGDRP at the next meeting or in writing.

E. Links with other international regulatory initiatives

IGDRP will develop and maintain strong, formal communication channels to the following international groups:

- The International Coalition of Medicines Regulatory Authorities (ICMRA) – in order to seek strategic guidance and resolution of barriers to progressing work that can only be resolved at the Heads of Agencies level.
- The International Pharmaceutical Regulators Forum (IPRF) – strong communication will strengthen the work of each of the groups while avoiding duplication of effort

The IGDRP will also remain open to considering engagement with others that might contribute to IGDRP work.

V. Funding

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

VI. Review

The performance and impact of the programme phase of the IGDRP will be assessed at the May 2016 meeting. These Terms of Reference will be reviewed concurrently and updated pending a decision on the future of the IGDRP post 2016.

Appendix A – List of IGDRP Members

- Agencia Nacional de Vigilancia Sanitaria (ANVISA)
- China Food and Drug Administration (CFDA)
- European Commission (EC)
- European Directorate for the Quality of Medicines and Healthcare (EDQM) (Observer)
- Federal Commission for the Protection against Sanitary Risk (COFEPRIS)
- Federal Service for Surveillance in Healthcare and Social Development
- Health Canada
- Health Sciences Authority (HSA)
- Ministry of Food and Drug Safety (MFDS)
- Ministry of Health, Labour and Welfare (MHLW)
- Medicines Control Council (MCC)
- Swissmedic
- Taiwan Food and Drug Administration (TFDA)
- Therapeutic Goods Administration (TGA)
- U.S. Food and Drug Administration (US FDA) (Observer)
- World Health Organization (WHO) (Observer)