International Generic Drug Regulators Programme

Terms of Reference

(Updated: 9 June 2017)

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

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

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[1] "Regulatory convergence" (hereinafter "convergence") means 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.

It is recognised that individual Regulatory Authorities (RAs) or Groups of RAs 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.

Activities will complement and not duplicate work undertaken in other international fora.

II. Operating Arrangements

A. IGDRP Membership

An RA or a Group of RAs can request to become Members or Observers of the IGDRP.

Membership or Observers to the IGDRP constitutes active participation on the Steering Committee (SC), plus the ability to request equivalent status on Working Groups (WG).

Members

Representatives of Members on the SC and WGs should have the requisite expertise, experience and ability to represent their RA or Group of RAs and contribute to progressing the programme, actively participate in face-to-face meetings or teleconferences, and work via email as necessary in order to most efficiently conduct work of the IGDRP.

Members shall have equal voice in decisions regarding the IGDRP.

Observers

Representatives of Observers on the SC and WGs should have the requisite expertise, experience and ability to represent their RA or Group of RAs and are encouraged to contribute to progressing the programme, actively participate in face-to-face meetings or teleconferences and work via email as necessary in order to most efficiently conduct work of the IGDRP.

Observers do not participate in decisions of the IGDRP.

Request for Member or Observer Status

An RA or a Group of RAs wishing to become an IGDRP Member or an Observer, shall submit a formal request using the IGDRP membership form, indicating their proposed contribution to the IGDRP, interest in specific Working Groups, and nominated representatives to act on behalf of the RA or Group of RAs.

A membership form is available on the IGDRP website for use by an RA or a Group of RAs. All fields on the membership form must be completed and provided to the IGDRP Secretariat at least 60 days before the next face to face meeting.

The IGDRP SC will consider all requests for Membership or Observers at the face to face meeting following receipt of a completed membership form. If endorsed, an RA or a Group of RAs will gain their Member of Observer status immediately following the face to face meeting.

An RA or a Group of RAs may attend the face –to- face meeting immediately following submission of a completed membership form, as a temporary Observer.

An RA or a Group of RAs that is a current Observer to the IGDRP and elects to become a Member of the IGDRP shall submit a formal request using the IGDRP membership form, indicating their proposed contribution to the IGDRP and interest in specific Working Groups at least 60 days before the next face to face meeting

An RA or a Group of RAs that is a current Member of the IGDRP and wishes to become an Observer of the IGDRP shall provide written notice to the IGDRP Secretariat at least 30 days before of the next face to face meeting.

An RA or a Group of RAs that is a current Member or Observer of the IGDRP and wishes to cease all participation in the IGDRP shall provide written notice to the IGDRP Secretariat at least 30 days before of the next face to face meeting.

A list of current IGDRP Members and Observers is shown at Appendix A.

External Experts

External experts may be consulted on an ad-hoc basis on topics for consideration by the SC or WGs.

A Member of the IGDRP requesting permission for an external expert to attend a SC or WG meeting shall provide a written request to the IGDRP Secretariat at least 30 days before the meeting, asking for SC to endorse their attendance.

External experts do not participate in decisions of the IGDRP.

Guests

An RA or a Group of RAs who are not Members or Observers of the IGDRP may request to attend a SC or WG meeting on an ad-hoc basis as a temporary Guest.

The concerned RA or Group of RAs shall provide a written request to the IGDRP Secretariat at least 30 days before the meeting, asking for SC to endorse their attendance.

Guests do not participate in decisions of the IGDRP.

B. Steering Committee (SC)

The SC:

- makes decisions on behalf of the IGDRP (only Members shall participate in decisions regarding 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 of at least one representative from each Member and Observer.

For consistency and continuity reasons each representative of an IGDRP Member or Observer should be fully knowledgeable on IGDRP matters.

a. SC Decision Making

All Members are committed to the goals and objectives of the IGDRP and to making best efforts to reach consensus. The Members of the SC will reach decisions by consensus (not voting) on matters related to the operation of the programme.

b. Chair and Co-Chairs

The Chair will rotate for each meeting and will be a Member of the SC. 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 will be responsible for the organisation of the meeting and for preparing a record of discussion.

C. Working Groups (WGs)

a. Creation/Disbanding of Working Groups

WGs may be established by the SC to undertake work on specific issues and activities.

A WG may be disbanded upon completion of its mandate or at the discretion of the SC.

b. WG Mandate and WG Work Plan

The mandate of a WG is reviewed and endorsed by the SC. The mandate must include the following information:

- General considerations & objectives;
- Scope; and
- Participating RAs and Groups of RAs (annexed).

The Work Plan describes the activities foreseen with short, medium and long term goals. The Work Plan must be presented to the SC for endorsement.

The WG should report to the SC on the progress and status of the activities undertaken.

c. Participation on Working Groups

Participation on WGs will be determined by the SC.

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

Representatives should be nominated by the respective IGDRP Members and Observers.

Members and Observers may "opt-out" from any WG or work plan activities by providing written notice to the relevant WG Chair and the IGDRP Secretariat.

D. Secretariat

a. Role

The responsibilities of the Secretariat include (but are not limited to):

- Facilitating and coordinating the work of the IGDRP;
- Disseminating information;
- Coordinating meetings;
- Maintaining a repository of documents using the IGDRP Secure Exchange Platform;
- Hosting and maintaining the IGDRP website, including associated costs;
- Co-ordinating the review of Terms of Reference (every two years or as required); and
- Processing the Membership and Observer requests in line with "IGDRP Membership" specified under section II (A) of the Terms of Reference.

The responsibilities of the Secretariat are provided for further in the IGDRP Secretariat Standard Operating Procedures.

b. Term and Nomination

Secretariat services will be provided by an IGDRP Member on voluntary consensus basis for a term of two (2) years, with possibility for an extension for one (1) additional year at the discretion of the current Secretariat, and endorsement by the SC.

Nominations for a new Secretariat will be sought 60 days prior to the end of the current Secretariat term. Nominations should be provided in writing to the current IGDRP Secretariat, for consideration and endorsement by the SC at the next face to face meeting.

The current IGDRP Secretariat will hand over all required information and responsibilities to the newly appointed Secretariat immediately following the face to face meeting.

III. Meetings

A. Steering Committee

The SC will meet face to face twice a year.

The SC will invite expressions of interest on a location of face to face meetings. The Regulatory Authority in the location at which the SC agrees to hold a meeting (hereafter: 'the host') will chair the meeting.

The date of meetings will be determined by the SC as advised by the host.

The SC may also hold ad hoc teleconferences as required.

B. Working Groups

The WGs will normally meet face to face twice a year within the margins of the SC meeting. These meetings should, where possible, be organised in conjunction with the SC meeting. Alternatively, meetings can be held in conjunction with an 'experts' conference where most WG members are attending. The WGs will also work remotely through telephone or web-conferences.

IV. Treatment of information and Communication

A. Language

The working language of the initiative is English. It is each Member and Observer's responsibility to translate any documents into additional languages as required.

B. Treatment of information

Information shared during IGDRP activities should be considered non-public information and handled in confidence by IGDRP Members, Observers, Guests and external experts, unless otherwise indicated.

All documents and information will be shared amongst IGDRP Members and Observers through a Secure Regulatory Exchange Platform.

Guests and external experts will receive the relevant documents for the meeting that they attend by email from the IGDRP Secretariat.

C. External communication

All external communication not already publicly available or pre-approved 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 and Observers shall make clear that their views expressed are their own views and not those of the IGDRP.

When an IGDRP Member or Observer accepts an invitation to represent the IGDRP at an international or other forum, the IGDRP 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 IGDRP. Documents and presentations delivered by a Member or Observer on behalf of the IGDRP should be endorsed by the SC prior to use.

The IGDRP Member or Observer 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, Observers, guests and external experts are responsible for all costs associated with participation at IGDRP meetings including all travel arrangements and accommodation.

VI. Review

The evaluation of the IGDRP will be assessed on a regular basis. The Terms of Reference will be reviewed every two years or as required following recommendation from the SC.

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

Appendix A – List of IGDRP Members and Observers

Members

- Agência Nacional de Vigilância Sanitária (ANVISA)
- China Food and Drug Administration (CFDA)
- European Union (European Commission + CMDh)
- Federal Commission for the Protection against Sanitary Risk (COFEPRIS)
- Federal Service for Surveillance in Healthcare and Social Development (ROSDRAVNADZOR)
- Health Canada
- Health Sciences Authority (HSA)
- Instituto Nacional de Vigilancia de Medicamentos y Alimentos (INVIMA)
- MedSafe
- Ministry of Food and Drug Safety (MFDS)
- Ministry of Health, Labour and Welfare (MHLW) / Pharmaceuticals and Medical Devices Agency (PMDA)
- South African Health Products Regulatory Agency (SAHPRA)
- Swissmedic
- Taiwan Food and Drug Administration (TFDA)
- Therapeutic Goods Administration (TGA)

Observers

- European Directorate for the Quality of Medicines and Healthcare (EDQM)
- U.S. Food and Drug Administration (US FDA)
- World Health Organization (WHO)