IGDRP
International Generic Drug Regulators Programme

INTERNATIONAL GENERIC DRUG REGULATORS PROGRAMME (IGDRP)

ROADMAP TO 2020

(2016-10-07)

IGDRP Roadmap to 2020

1. INTRODUCTION

1.1 Background

The availability of quality generic medicines plays an increasingly important role in helping to address rising health care costs and in promoting access to essential medicines worldwide. This, however, has led to significant pressures on regulatory authorities (RAs) tasked with the review and authorisation of these drug products. In addition to an increased workload associated with the growing number of generic drug applications, RAs must also contend with more sophisticated generic drug products and issues associated with complex global production and distribution chains.

Given these challenges, the benefits of regulatory cooperation, convergence and harmonisation has long been recognised. "Regulatory convergence" represents a process whereby the regulatory requirements and approaches across countries and regions become aligned over time as the same harmonised technical guidance documents, standards and scientific principles are adopted and similar regulatory practices and procedures are introduced. Regulatory convergence, in turn, makes it possible for additional enhanced forms of cooperation and collaboration between RAs.

What are some of the drivers for international regulatory cooperation and convergence?

The environment in which international RAs undertake their regulatory activities for generic medicines is influenced by several key drivers, including:

- New and emerging science, medicines and technologies;
- Globalisation of issues and production chains;
- Emerging public health threats and needs;
- Sustainability and appropriateness of regulatory systems and oversight;
- Need to support risk-based and science-based review functions;
- Interest and the need for international alignment and sharing of best practices;
- Governmental initiatives for regulatory convergence and cooperation;
- Need for modernised information sharing systems;
- Public demand for greater openness and transparency and availability of information to make informed decisions.

The official launch of the *International Generic Drug Regulators Pilot (IGDRP)*[1] in 2012 marked a shared interest and commitment by a consortium of RAs to explore potential information and work sharing opportunities in the area of generic medicines. Following a successful three-year pilot (2012-2014) and continued interest to collaborate, a group of regulators launched the renamed *International Generic Drug Regulators Programme (IGDRP)* in 2015 aimed at regulatory convergence and cooperation in this area.

[1] WHO Drug Information Vol. 28 No. 1, 2014

Among other objectives, the IGDRP initiative has the ambition to increase efficiency of review procedures and reduce regulatory burden without comprising the safety, efficacy, and quality of generic medicines.

As reflected in its *Terms of Reference*[2], the IGDRP is guided by its:

> ***Mission:*** *To promote collaboration and regulatory convergence in the area of generic drug regulation in order to strengthen the ability of health authorities to meet their respective mandates.*
>
> ***Goal:*** *To facilitate efficient use of resources, timely authorisation and availability of safe, effective and high quality generic drug products.*

The following key regulatory analysis surveys have been published which were conducted to identify similarities and differences in technical requirements and/or regulatory practices amongst the IGDRP members:

- IGDRP Generic Drug Product Regulatory Gap Analysis[3];
- International Guidelines for Bioequivalence of Systemically Available Orally Administered Generic Drug Products: A Survey of Similarities and Differences[4];
- Similarities and Differences of International Practices and Procedures for the Regulation for Active Substance Master Files/Drug Master Files of Human Use: Moving Toward Regulatory Convergence[5].

The knowledge gained in these surveys and reflected in these references will be central in identifying challenges and opportunities for effective regulatory collaboration.

1.2 Purpose

The purpose of this *IGDRP Roadmap to 2020* is to make available a strategic vision to articulate and guide the collective efforts of IGDRP in terms of *where we are going* and *how we are going to get there*.

It provides overarching concepts for the strategic priorities, describes inter-dependencies, as well the key objectives that will facilitate an assessment of the success of meeting our common goals.

Throughout the process of regulatory convergence and cooperation, a key commitment reflected within the IGDRP Roadmap is to work openly and transparently with regulatory authorities, stakeholders and other international partners.

The success of a regulatory authority in establishing a sustainable regulatory programme for meeting its objectives is founded on ensuring that effective operational requirements and procedures are in place and delivered in a timely and effective manner. These include elements relating to having adequate human resources, IT infrastructure, guidance documents and regulatory tools, and training programmes.

[2] http://igdrp.com/about-us
[3] WHO Drug Information Vol. 30, No. 3, 2016
[4] AAPS Journal, Vol. 15, No. 4, October 2013
[5] J Pharm Pharm Sci, (2) 290 - 300, 2016

1.3 Scope

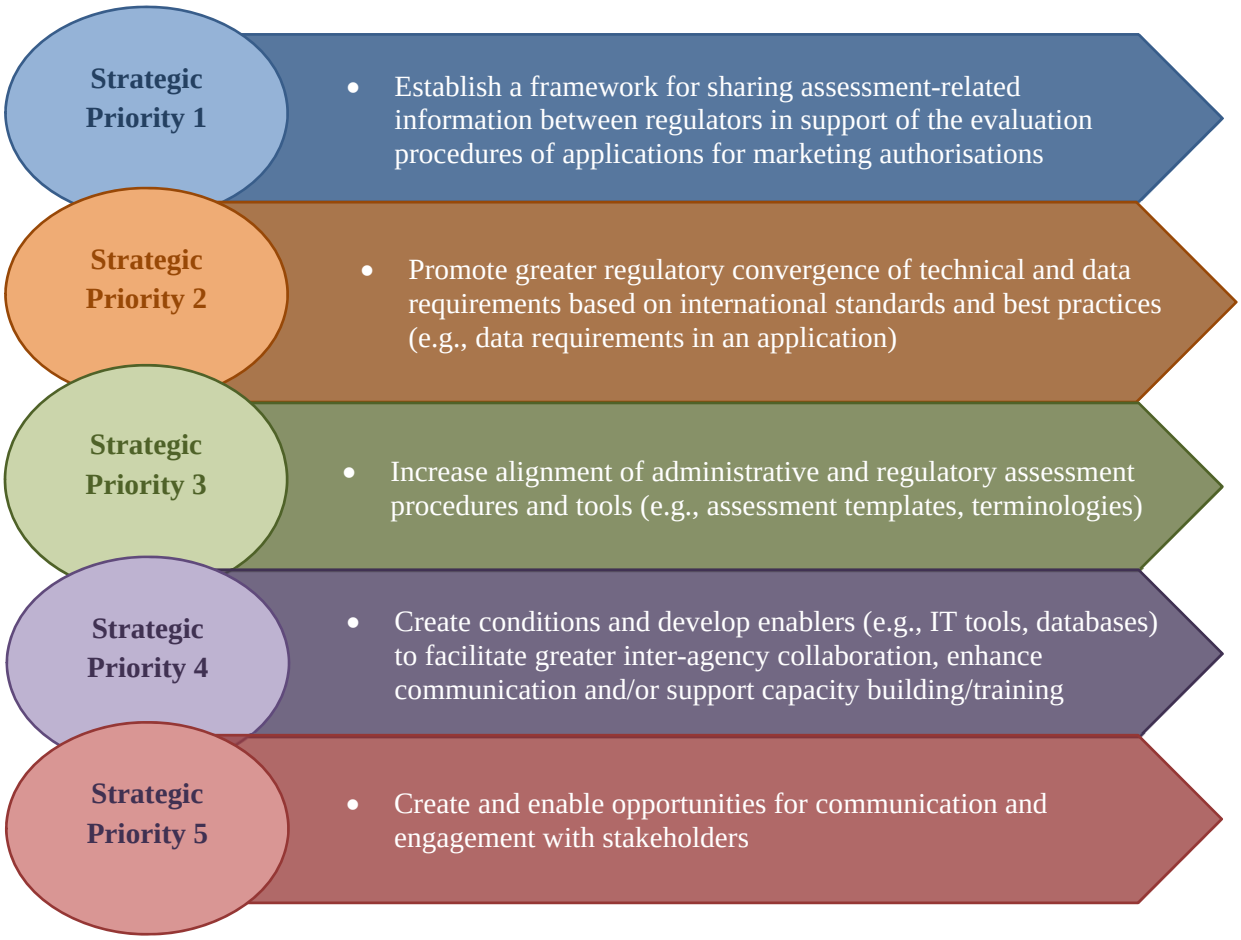
The scope of the initiatives within this IGDRP Roadmap is aligned with the scope of the activities reflected in the agreed upon *IGDRP Terms of Reference*.

The IGDRP will undertake activities that best meet the needs of the IGDRP members in the area of generic drug regulation. 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 the various objectives are met in an efficient and effective manner.

These IGDRP activities will complement and not duplicate work undertaken elsewhere. Once the strategic priorities will be approved, a review of relevant existing international fora will be carried out in order to identify potential synergies and avoid situations of duplication. In case where such situations of duplication are identified, IGDRP will liaise with the fora in order to take a decision on the most efficient way to undertake these activities.

2. IGDRP Strategic Priorities

Following is a series of strategic priorities that have been developed in response to these challenges and demands on regulatory programmes for generic medicines and for guiding the activities of the IGDRP initiative.



Details on these strategic priorities, including specific objectives, are described below.

- **Strategic Priority 1 - Establish a framework for sharing assessment-related information between regulators in support of the evaluation procedures of applications for marketing authorisations:**

    - *The creation of an efficient and effective regulatory information sharing model for generic medicines that is responsive to emerging challenges will support the timely market entry of safe, effective, and high quality generic medicines.*

        - Objective 1.1 – Pursue the ongoing pilot on information sharing and, based on lessons learned, further develop information and work sharing initiatives between IGDRP members that support authorisation procedures.

- **Strategic Priority 2 - Promote greater regulatory convergence of technical and data requirements based on international standards and best practices (e.g., data requirements in an application):**

    - *Improving the effectiveness and efficiency of the assessment of applications can be achieved by aligning technical requirements, improving the quality of dossiers, developing good review practices, with a focus in the areas where there is a lack of common regulatory requirements.*

        - Objective 2.1 – conduct surveys and develop reference materials summarising the similarities and differences between the RAs on topics of interest with a view to identify areas of potential regulatory convergence or harmonisation for domestic guidelines;
        - Objective 2.2 – strengthen and build a strong business cases for staff exchange;
        - Objective 2.3 – provide the opportunities for IGDRP members to discuss technical issues during the working group meetings.

- **Strategic Priority 3 - Increase alignment of administrative and regulatory assessment procedures and tools (e.g., assessment templates, terminologies):**

    - *The alignment of administrative and regulatory procedures between regulators is an indispensable and essential element for reaching the IGDRP goals.*

        - Objective 3.1 – develop the regulatory tools in the different working groups that allow for the alignment requirements and common understanding between the regulators;
        - Objective 3.2 – validate the usefulness of the procedures and tools (e.g., through piloting and the implementation of the tools);
        - Objective 3.3 – promote the procedures during virtual or face to face meetings to develop programs, platforms and instruments for continuous resource formation.

- **Strategic Priority 4 - Create conditions and develop enablers (e.g., IT tools, databases) to facilitate greater inter-agency collaboration, enhance communication and/or support capacity building/training:**

    - *Developing efficient communication and interactions amongst regulators are essential elements to meet the goals of IGDRP. This will help to provide a common understanding of technical and regulatory requirements and allowing exchange of information on other topics of interest for generic drug products.*

      Collaboration and regulatory convergence among IGDRP members relies to a great extent upon an accurate understanding of IGDRP members' regulatory processes and confidence in IGDRP members' assessment practices. To achieve this goal, specific activities should be undertaken to build confidence and understanding. Since IGDRP members have different levels of experience, there is also a need to undertake specific capacity building in order to ensure a common understanding of the technical issues that the IGDRP faces.

        - Objective 4.1 – develop tools/mechanisms to exchange assessment reports and other document that may contain Confidential Business Information (CBI) between regulators and enhance the use of a secure IT platform or other appropriate tools. Due to different legal and regulatory procedures, it is essential that issues concerning CBI are addressed and that authorities/organisations can exchange such information in an efficient manner (with notable linkages to Strategic Priority 1);
        - Objective 4.2 - develop databases to identify common Active Substance Master Files (ASMFs)/Drug Master Files (DMFs) and applications submitted to RAs to register generic medicines;
        - Objective 4.2 – Promote information sharing during regular virtual or face-to-face meetings, and establish lists of contact points and communication channels between agencies/organisations;
        - Objective 4.3 – promote available training resources and support capacity building activities to enhance the development of human resources and competencies for less experienced regulators (e.g., for existing and potential new members);
        - Objective 4.4 – enable capacity building activities (e.g., with a joint review of the Quality or Bioequivalence information in a generic application) to better understand the interpretation and application of regulatory procedures and commonly utilised guidance documents.

- **Strategic Priority 5 - Create and enable opportunities for communication and engagement with stakeholders:**

    - *It is recognized that the activities within IGDRP are driven by the participating regulatory authorities and that stakeholders do have an important role in the availability of safe, effective, and high quality generic medicines. Stakeholder participation in IGDRP initiatives is only possible if they are aware of these activities and understand the purpose and benefit these will bring to them. These interested parties are an important source of information that needs to be considered when developing IGDRP initiatives.*

Engagement with stakeholders (e.g., the pharmaceutical industry) is an effective way of promoting transparency of the IGDRP initiatives and can occur on multiple levels. The engagement strategies include communication with domestic parties, international meetings or associations, journal articles, IGDRP fora, and not least via the IGDRP website. It is important that consistent messages are communicated to industry in a timely manner.

- Objective 5.1 - ensure that stakeholder involvement and the need for communication is considered routinely as part of IGDRP initiatives;
- Objective 5.2 - agree and maintain key messages for use by members and the IGDRP Secretariat during engagement within stakeholders;
- Objective 5.3- identify key meetings at which time information sharing on the IGDRP activities would be desirable;
- Objective 5.4 - create a common IGDRP brand for use by members when making presentations and publishing materials (e.g., templates for documents, presentations);
- Objective 5.5 - create and enhance the IGDRP website as means for notify stakeholders of initiatives and outputs.

3. How Will We Get There

3.1 Linkages/Future Directions

The success of the IGDRP activities is predicated on effective collaboration and communication. This active engagement would involve interactions not only with interested parties from the generic pharmaceutical industry, but will also require links with other international regulatory initiatives.

The IGDRP will develop and maintain strong, formal communication channels with the International Coalition of Medicines Regulatory Authorities (ICMRA) – in order to seek strategic guidance that can be resolved at the Heads of Agencies level.

In addition, strong communication and collaboration with the International Pharmaceutical Regulators Forum (IPRF) will continue to strengthen the work of each of these groups while avoiding duplication of effort.

It is acknowledged that discussions are currently ongoing between the IGDRP and IPRF to explore and enable greater collaboration. The results of these discussions will guide the future model(s) of these initiatives.

The IGDRP will also remain open to considering engagement with other initiatives that might contribute to IGDRP work and fulfilling its objectives.

3.2 Assessment of Impact

Performance measurement is the ongoing process of developing and using metrics and tools to monitor and assess progress in achieving the predetermined goals for the IGDRP initiative. The resulting data is used for program management, evaluations, audits, strategic reviews, and reporting. Performance measurement is a critical part of the program management cycle and, by establishing a strong performance culture, regulatory authorities are better able to measure the impact, improve practices, and measure the changes that will come as a result of the IGRDP initiatives.[6]

Program performance is measured in order to support ongoing program improvement and informed decision making. It will also facilitate reporting requirements and will provide evidence for evaluations, audits, and strategic reviews (e.g., showing evidence that the program is relevant, continues to be needed, and is achieving expected results).

The performance and impact of the programme will be assessed at periodic stages against the stated objectives under each of the Strategic Priorities. An *IGDRP Logic Model* and an *IGDRP Results and Data Matrix* have been developed to assist in evaluating the effectiveness of the programme.

A logic model has the following four components[7]:

- *Inputs:* what resources go into the IGDRP initiative;
- *Activities:* the actions or work that the IGDRP initiative undertakes;
- *Outputs:* products, reports, and services delivered or produced to clients through those activities;
- *Outcomes:* the changes or benefits in clients or communities that are a result of the IGDRP initiative's activities and outputs.

The logic model provides a schematic representation depicting the linkages between the activities and the expected sequence of outcomes over the life of the IGDRP initiative. The logic model is a flowchart that summarizes the key elements of the initiative, the resources and other inputs, the activities, and the intermediate and end outcomes (shorter and longer term results) that the IGDRP initiative hopes to achieve. The logic model shows the assumed cause and effect linkages among the elements in the model and demonstrates which activities are expected to lead to which outcomes.[8]

These tools will be helpful in determining the success of the intended objectives against the results achieved.

[6] Wholey, JS; Hatry, HP; and Newcomer, KE. San Francisco: Jossey-Bass (2010); Handbook of Practical Program Evaluation, 3rd Edition

[7] W. K. Kellogg Foundation (2001). W. K. Kellogg Foundation Logic Model Development Guide

[8] Pawson, R; London: Sage (2006). Evidence Based Policy