IPRP
International Pharmaceutical Regulators Programme

IPRP Strategic Vision

2025 - 2027

1. Overview

1.1 Drivers for Regulatory Cooperation, Convergence and Reliance among Regulators

What is the regulatory context?

The availability of safe, effective and quality medicinal products for human use plays an increasingly important role in contributing to sustainable health care systems worldwide. The rapid pace of innovation in human medicines, with the emergence of complex biological molecules, advanced medicinal therapies, biosimilars, complex generic formulations, 3D printing, personalized medicines, complex global production and distribution chains, and other trends, place significant pressures on regulatory authorities (RAs) and regulatory organisations (ROs) tasked with the review, coordination and/or authorisation of these medicinal products. In addition to increased workload demands, RAs and ROs must also effectively oversee increasingly advanced medicinal products and issues associated with complex global production and distribution chains.

In addition, emerging public health threats and the public's demand for access to information and greater transparency of government operations and decisions, overlay additional pressures on RAs and ROs.

Given these challenges, the benefits of regulatory cooperation, convergence, reliance and information sharing have long been recognised. "Regulatory convergence" represents a process whereby the regulatory requirements and approaches across countries and regions become more similar or 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 is an enabler for enhanced forms of cooperation and collaboration between RAs and ROs and may also better position them for the possibility of applying reliance and work sharing. "Regulatory reliance" in turn is a concept that has gained significant momentum over the past years with more and more RAs and ROs developing reliance frameworks and approaches. Reliance is defined in the WHO Good Regulatory Practices as the act whereby a regulatory authority in one jurisdiction takes into account and gives significant weight to assessments by another regulatory authority or trusted institution or to any other authoritative information in reaching its own decision. The relying authority remains independent, responsible and accountable for the decisions taken, even when it relies on the decisions, assessments and information of others[1]. In addition to the finalisation of a global standard, the WHO Good Reliance Practices[2], the WHO has also started to designate WHO Listed Authorities (WLAs)[3], replacing the "Stringent Regulatory Authorities" (SRAs), as authorities which others may rely upon.

The *International Pharmaceutical Regulators Programme* (IPRP) was officially launched on January 1st 2018, following the consolidation of the International Pharmaceutical Regulators Forum and the International Generic Drug Regulators Programme. IPRP is expected to create an environment for its members and observers to exchange information on issues of mutual interest and enable cooperation amongst regulatory authorities and organisations in the increasingly complex global context of pharmaceutical regulation. The goal is to create a regulatory forum that covers all medicinal pharmaceutical products, maximise synergies, avoid duplication of effort, and enable closer linkages with other initiatives to simplify the numerous forms of international regulatory cooperation. It is envisioned that IPRP will become the global regulators-only venue for discussion of operational issues related to pharmaceutical regulation.

1.2 Purpose

[1] https://www.who.int/publications/m/item/annex-11-trs-1033
[2] https://www.who.int/publications/m/item/annex-10-trs-1033
[3] https://www.who.int/initiatives/who-listed-authority-reg-authorities

This document articulates a vision for the work to be completed by IPRP and guides the collective efforts of its members and observers. It presents IPRP's strategic priorities and articulates how IPRP will work to progress in each area.

1.3 Scope

The scope of initiatives under this IPRP Strategic Vision is aligned with the scope of activities as outlined in the IPRP Terms of Reference. This pertains to medicinal products for human use ("pharmaceuticals") including but not limited to: innovator pharmaceuticals, cell and gene therapies, biosimilars, biologics, generic pharmaceuticals, and nanomedicines.

IPRP operates on a voluntary basis; therefore, the adoption and use of IPRP work products is voluntary and participating members and observers may decide on their level of participation in IPRP activities. The deliverables produced by IPRP reflect the views of the participating subject matter experts and should not be construed to represent the official views of any given regulatory authority or regulatory organisation.

2. Vision and Mission

IPRP's work is guided by its mission and vision statement.

Vision Statement:

The IPRP is the global forum of regulatory authorities and regulatory organisations at the operational level for issues related to the regulation of pharmaceuticals for human use. IPRP offers tangible benefits for its members and observers and is committed to promoting regulatory science, sharing information and best practices, and collaboration to advance public health, facilitate access to medicines and address emerging regulatory challenges of mutual interest.

Mission Statement

The International Pharmaceutical Regulators Programme (IPRP) promotes regulatory convergence and reliance by means of practical and operational information exchange which fosters trust and a mutual understanding of the range of challenges and contexts facing each regulatory authority.

This is done in order to enhance the health of our populations by the most efficient means possible and is achieved by:

- Creating a trusting environment for regulators to exchange information on issues of mutual concern,
- Working closely with other international organisations to further extend the benefits of international regulatory collaboration,
- Providing effective support for our common activities,
- Regularly communicating our respective activities and sharing our lessons learned, and
- Encouraging engagement and consultation with our regulatory stakeholders when appropriate.

3. Core Activities

The following core activities exemplify how the work under IPRP contributes to its mission and vision.

1) ***Promoting efficiency, regulatory convergence and reliance by sharing best practices and developing tools as a resource for regulators to assist in regulatory review for IPRP's portfolio of drug products*** – IPRP members and observers share regional review processes and identify best practices that can be applied in regulatory review and develop templates and tools for assessment and establishment of good review practices. Examples include the *Biopharmaceutics Classification System (BCS) Biowaiver Assessment Report Template*, created to ensure that the relevant information for a BCS biowaiver is consistently taken into consideration during an assessment. Additionally, the *Guidance for Quality Assessors – Drug Substance* was created to assist Quality Assessors in the review of the technical information contained in the Quality Module (Module 3) of Active Substance Master Files/Drug Master Files and marketing authorisation applications. The results of a survey among IPRP members and observers on their reliance frameworks and approaches has been published on the IPRP website and is a valuable resource for both regulators and industry.

2) ***Addressing challenges and sharing experiences associated with the implementation of ICH guidelines*** – IPRP provides an opportunity for regulators to share regional experiences and challenges related to the implementation of ICH guidelines. These challenges can be addressed by sharing best practices and promoting available training materials. Additionally, IPRP promotes a common understanding of ICH guidelines to help foster consistency in the implementation of those guidelines globally.

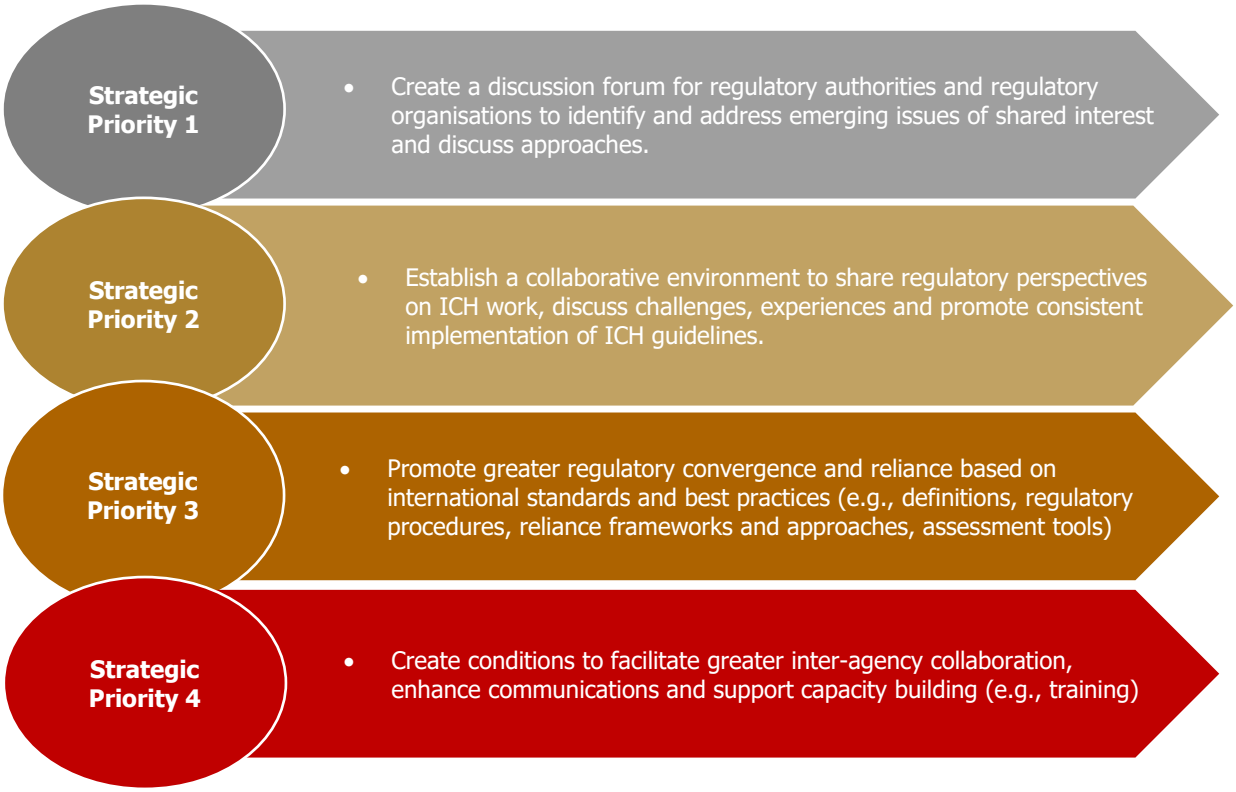
3) ***Identifying areas of potential regulatory convergence, opportunities for harmonisation and areas where a lack of common regulatory requirements exists*** – In order to understand where opportunities exist for RAs and ROs to align and converge, an understanding of the differences and similarities between regional regulatory frameworks must first be attained. This understanding can also facilitate identification of opportunities for harmonization in other regulatory forums such as ICH. To achieve this purpose, IPRP compiles regional regulatory frameworks, classification systems, and conducts mapping of scientific and regulatory terminology used in IPRP member and observer regions. Additionally, IPRP's members and observers share updates related to regional regulations and guidance. Through this work, areas can be identified where regulatory convergence is possible and where a lack of common regulatory requirements may exist.

   Examples of work to better understand regional regulatory frameworks include the *Mapping and exchange of requirements for nanomedicines / nanotechnology in drug product class specific guidance (e.g. liposomal formulations)* intended to identify regional synergies and differences in requirements for nano drug products; the *International Regulatory Perspectives: Degree of Regulatory Oversight for Eight Categories of Cell Therapy Products* which compares regional regulatory frameworks for cell therapies; and the *IGDRP generic drug product regulatory gap analysis - Regulatory collaboration (WHO Drug Information Vol. 30, No. 3, 2016)* developed to identify regulatory similarities amongst participating members and observers as well as gaps that might create challenges for collaboration.

4) ***Creating efficient and effective regulatory information sharing models*** **–** IPRP creates opportunities for efficient information sharing models to support regulator-to-regulator, non-confidential, sharing of documents such as assessment reports. These frameworks can be used to support evaluation procedures of applications for marketing authorizations.

4. Strategic Priorities

The strategic priorities presented here have been established to create a pathway for IPRP to achieve its goals in responding to the challenges and demands faced by RAs and ROs:



Strategic Priority 1

Create a discussion forum for regulatory authorities and regulatory organisations to identify and address emerging issues of shared interest and discuss approaches

All aspects of a pharmaceutical's life-cycle, from development to manufacture to post-market pharmacovigilance, has become increasingly complex and globalised. Regulatory authorities are often faced with the same or similar challenges, including increasingly limited resources. Regulatory exchange allows RAs and ROs to build on each other's strengths to foster innovation and ensure access to medicines while employing approaches focused on minimizing risks and optimizing public health outcomes.

IPRP strives to:

- Increase awareness and understanding of emerging regulatory issues
- Identify best practices for how to address emerging public health issues related to the regulation of pharmaceuticals
- Establish itself as a forum for open discussion for the exchange of non-confidential information

Strategic Priority 2

Establish a collaborative environment to share regulatory perspectives on ICH work, discuss challenges, share experiences, and promote consistent implementation of ICH Guidelines

While the International Council for Harmonisation (ICH) is the leading forum for harmonisation of technical requirements for the regulation of pharmaceuticals, its success is dependent upon consistent implementation of its guidelines globally. The IPRP provides a unique opportunity for RAs and ROs to discuss developments under ICH, communicate perspectives, and share best practices for the successful implementation of ICH guidelines. Additionally, IPRP also allows for information exchange leading to a better understanding of regional regulatory frameworks and thus identification of areas where harmonisation may be feasible as well as areas where a lack of common regulatory requirements exist, before topics are brought to ICH. This exchange can help promote a more informed and aligned approach of regulatory parties, globally, which can help foster efficiency in the development of guidelines and standards.

IPRP strives to:

- Promote discussion of common challenges associated with the implementation of ICH guidelines and share strategies, experiences, and best practices to overcome obstacles
- Promote more consistent and broader implementation of ICH guidelines
- Support the identification of unmet needs and priorities for new topics for regulatory harmonization under ICH
- Increase awareness on available training on ICH guidelines
- Increase awareness and understanding of international standards by the regulated industry

Strategic Priority 3

Promote greater regulatory convergence and reliance based on international standards and best practices (e.g., definitions, regulatory procedures, reliance frameworks and approaches, assessment tools)

Improving the effectiveness and efficiency of the assessment of applications can increase access to products of assured quality, safety, and efficacy. This can be achieved by aligning technical requirements, improving the quality of dossiers, developing effective reliance frameworks and approaches, and applying good review practices. Hence, greater collaboration can lead to regulatory convergence, increased trust and efficiency in regulatory assessment and can facilitate reliance globally.

IPRP strives to:

- Communicate the current thinking of RAs and ROs of different regions on standards for acceptable product performance and standards for acceptable evidence in the regulation of pharmaceuticals
- Clarify how and why regional review practices can add value to regulatory business processes and to quality and effectiveness of shared regulatory functions
- Develop tools to aid in regulatory assessment such as review frameworks and structured review work products and reports for use by RAs and ROs globally
- Promote consensus on good regulatory practices and good reliance practices
- Develop frameworks to facilitate sharing of regulatory information, including that which will support evaluation procedures of applications for marketing authorizations

Strategic Priority 4

Create conditions to facilitate greater inter-agency collaboration, enhance communications, and support capacity building (e.g. training)

IPRP provides its members and observers with a unique opportunity to leverage the expert scientific knowledge, regulatory and operational experience, and information access of other participating regulators. In order to maximise these benefits, IPRP aims to establish an environment for open communication and discussion and encourage engagement among RAs and ROs.

IPRP strives to:

- Establish IPRP as an international networking forum to discuss scientific developments and concerns for the regulation of medicinal products
- Share regional updates and developments in guidelines, science, and regulatory advancements (e.g. through lists of regulatory frameworks, compilation of classifications systems, and mapping of terminology, existing guidance, and regulation)
- Communicate strategies for ensuring appropriate staffing and available expertise to meet regulatory review needs
- Enable capacity building activities to better understand the interpretation and application of regulatory procedures and commonly utilised guidance documents
- Promote use of available training resources and identify areas where a need for training may exist

5. Communication and Evaluation

5.1 Communication

The success of IPRP's activities is centred on good communication practices & effective collaboration among stakeholders. Stated goals & objectives will be achieved through exchange of information & communication at biannual face-to-face or teleconferences meetings of management committee, meetings of IPRP working groups, posting information & IPRP work products & announcements on the IPRP website.

Good communication practices have strategic value for IPRP work as they are:

- Promoting Global Regulatory Convergence
  Effective communication helps align regulatory expectations across different jurisdictions and facilitates dialogue on scientific and technical issues, reducing duplication of regulatory efforts.

- Building Trust and Transparency
  Open communication between regulators, industry, and stakeholders fosters confidence in regulatory systems. Transparency strengthens credibility of IPRP as a platform for collaboration.

- Facilitating Knowledge Sharing
  Communication channels (workshops, publications, reports) enable exchange of best practices and lessons learned. Communication also enhances collective problem-solving in areas like quality, safety, and efficacy.

- Supporting Innovation
  Clear communication pathways accelerate regulatory understanding of emerging technologies (e.g., advanced therapies, digital health) and ensure consistent messaging to innovators, reducing uncertainty.

- Enhancing Stakeholder Engagement
  Communication strategies help include patients, healthcare professionals, and industry voices and improve relevance and acceptance of IPRP outputs.

- Strengthening Global Preparedness
  Timely and coordinated communication supports rapid regulatory response to public health crises and ensures harmonized guidance during emergencies (e.g., pandemics, drug shortages).

- Maximizing Impact of IPRP Outputs
  Well-structured communication ensures that recommendations, guidelines, and reports reach the right audiences. Increases adoption of IPRP work products across member agencies.

5.2 Evaluation

IPRP will revisit its strategic priorities periodically to assess how well the work of the working groups and the management committee support the stated IPRP objectives. Additionally, IPRP will reassess its objectives and consider any need for realignment with the regulatory landscape as markets evolve and technology and innovation continue to advance and challenge the regulation of pharmaceuticals globally.