FIFARMA

FIFARMA Position Paper - Good Regulatory Practices: enabling regulatory efficiencies to deliver medicines in a timely manner to Latin America and the Caribbean

FIFARMA members represent the innovative pharmaceutical industry and country trade associations in the Latin American and Caribbean Region. FIFARMA is fully supportive of the World Health Organization (WHO) Triple Billion Targets of 1 billion more people benefitting from universal health coverage; 1 billion more people better protected from health emergencies and 1 billion more people enjoying better health and well-being. FIFARMA is committed to engage in the development of policies that foster ecosystems that promotes innovation and the sustainability of health systems in the benefit of patients in Latin America and the Caribbean.

Strong regulatory systems support better public health outcomes

> ***Regulators are an essential part of the health workforce, and inefficient regulatory systems themselves can be a barrier to access to safe, effective and quality medical products.***
>
> World Health Assembly Resolution 67.20

For delivering WHO targets, strong regulatory systems are foundational, with regulators supported by an effective framework of laws, regulations and guidelines and that they have the competence, capacity, resources and scientific knowledge to deliver their mandate in an efficient and transparent manner. The extent to which a regulatory framework fulfills its policy objectives depends on the quality of its development and implementation - and Good Regulatory Practices (GRP) represent a set of principles and practices applied for improving the quality of regulations and the achievement of their desired outcome. WHO[1] and the Pan American Health Organization (PAHO)[2] recognize the value of GRP, inviting Member States to integrate principles of GRP in their regulatory systems and considering establishing roadmaps, in consultation with stakeholders, to monitor progress in implementation. The ability to demonstrate consistent adherence to GRP principles is also a key part of the regulatory Performance Evaluation Process (PEP) that WHO uses to define Listed Authorities (WLA), and therefore a hallmark of any trusted regulator. FIFARMA endorses WHO's GRP guidelines[3] and encourages the adoption of GRP by regulators in Latin America and the Caribbean as a tool to strengthen regulatory systems and thus supporting improved public health outcomes.

Areas of opportunity to strengthen GRP implementation in Latin America and the Caribbean

FIFARMA recognizes that, to different degrees, National Regulatory Authorities (NRAs) in Latin America and the Caribbean make use of different tools and procedures related to GRP. Moreover, FIFARMA recognizes that some of the principles of GRP depend on decisions and activities that might go beyond the scope of action of the regulatory authority. However, upon evaluation of the GPR principles and recommendations contained in the WHO guidelines, FIFARMA understands that there

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[1] Recommendations of Extraordinary Virtual International Conference of Drug Regulatory Authorities (ICDRA), 2021.

[2] Report "Regulatory System Strengthening in the Americas: Lessons Learned from the National Regulatory Authorities of Regional Reference", 2021.

[3] Good Regulatory Practices in the regulation of medical products. WHO Technical Report Series, No. 1033, Annex 11, 2021.

are numerous opportunities for regulators in the Region for greater adherence to these practices, in the following four key areas:

> ***The application of the principles of GRP during the surveillance and the lifecycle of the product is encouraged.***
>
> IX PANDRH Conference Recommendation

1. **Embed transparency** initiatives and principles

Transparency is a key principle to embed within NRAs. All stakeholders including patients, payers, the medical community and industry will benefit from transparency initiatives adopted by NRAs. Transparently developed regulations foster trust with stakeholders including patients in the evaluation and approval of medicines. FIFARMA considers transparency of the products approval process and across the product life-cycle crucial elements to ensure impartiality to be incorporated by regulators. This will increase process predictability and stakeholder confidence in medicines and other regulated products.

2. **Ensure consistency** in the application of regulatory guidance

As recognized by WHO, consistency in developing, implementing and enforcing regulations is central to GRP. FIFARMA supports the WHO recommendation that '*new regulations should complement, and not conflict with, existing regulatory instruments*' and recommends NRAs to identify opportunities to leverage international guidance. FIFARMA believes that strengthening international regulatory cooperation benefits regulators, and implementation of GRP underpin and facilitates such cooperation programs, as well as compliance with international treaty obligations and regional agreements. GRP promote the rationalization of technical requirements, which supports convergence, reliance and harmonization activities.

3. **Embrace technology** to support GRP

Technology improvements and digitalization provide an opportunity to support the implementation of mechanisms and embed earlier adoption and monitoring of some aspects of GRP. Examples include opportunities to strengthen communication with the regulated sector, information sharing, and transparency.

4. **Support innovation** driven by scientific progress

GRP support a degree of flexibility within the regulatory environment to ensure that regulatory standards recognize emerging scientific innovation, while not compromising the efficacy, safety and quality of medicinal products. Such flexibility is possible based on the difference between statutory laws and guidelines. While the legal framework establishes general rules of law, guidelines complement those rules by providing technical details to the regulated sector. This would allow regulators to keep the pace of scientific progress and by updating regulatory standards and requirements in guidelines without the need to amend the underlying law.

Taking these four areas of opportunity into consideration, and considering the best practices observed by FIFARMA member companies when working with regulators across the globe, we propose the following recommendations are considered for adoption by regulators in Latin America and the Caribbean to improve adherence to GRP in the region. FIFARMA is willing to provide examples of these best practices and collaborate with regulators and other stakeholders for their local implementation.

Call for action: practical recommendations on GRP implementation by regulators in Latin America and the Caribbean

For the regulatory performance:

- Use the WHO Global Benchmarking Tool (GBT) to identify strengths and areas for improvement.
- Formulate institutional development plans (IDP) to build upon strengths and address the identified gaps, in close collaboration with WHO, PAHO, and industry.
- Implement Quality Management Systems (QMS) to allow for the continuous review of internal procedures.
- Develop strategic objectives and indicators to monitor progress and achievements.
- Publishing annual reports to give transparency to the regulatory performance and results.
- Develop business continuity and crisis management plans to prepare for unforeseen events that disrupt the routine of the regulator (i.e. natural disasters, cyber-attacks, public emergencies).

For new and revised regulations:

- Adoption of a Regulatory agenda to identify short, medium, long-term priorities.
- Develop and revise regulations to converge with international guidelines and standards.
- 60-day commenting periods for public consultations to ensure all interested parties and international stakeholders can provide feedback in a robust manner.
- Publish information on the status of regulations that are in review process.
- Adopt implementation plans for newly adopted regulations.

For submissions:

- Adoption of pre-submission meetings that facilitate planning for submissions, streamline review, and manage timeframes and resources for industry and regulator.
- Define clear and feasible timelines for assessment, questions, and final decision.
- Use digital platforms to enable the tracking of regulatory submissions by industry.
- Use of regulatory reliance strategies to enable a more efficient use of internal resources.
- Publication of assessment reports that inform criteria for decision-making.

The value of Good Regulatory Practices in public health emergencies

WHO guidelines state that regulatory oversight should not be prescriptive but rather be flexible in responding to an evolving environment and unforeseen circumstances, being prepared to provide timely responses to urgent situations. The lessons learned from around the globe with the use of different regulatory agilities during the COVID-19 pandemic offer an opportunity for regulators to review, streamline, and adjust their national regulations, where/when appropriate. These lessons help to prepare for future public health emergencies. In Latin America, an assessment of PAHO's summary of the measures implemented by regulators for COVID-19 indicate that appropriate regulatory response included increased use of GRP principles – mainly **proportionality** (regulations adequate to the risk of the product and the urgency of the situation), **flexibility** (regulation able to reflect or respond to changes in the regulated environment, such as evolving science and technology and emergencies), **clarity** (regulations and basis for taking regulatory decisions are understood), **efficiency** (adequate use of limited resources; use of reliance, work-sharing and alignment of regulatory requirements to international standards), and **transparency** (increased

> ***Regulatory authorities […] must establish and implement a coherent regulatory framework to provide the required level of oversight and control while facilitating innovation and access [and] they must also build the necessary flexibility and responsiveness into the regulatory framework, particularly for managing public health emergencies.***
>
> WHO GRP Guidelines

communication with stakeholders; information sharing among regulators; use of virtual strategies and digital tools).

FIFARMA's commitment to increased regulatory efficiency and transparency

The companies that are members of FIFARMA recognize that there is a role for industry in implementing Good Regulatory Practices and creating a culture that allows GRP to advance. For that, we take this opportunity to reinforce our commitment to continue to work ethically and promote trust of regulators in our practices; support local authorities in developing regulations and practices that are convergent with international guidelines and standards; supply high-quality applications and regulatory documentation, based on sound science; respect and promote the technical and operational autonomy of the decision making process of regulators; cooperate with regulators for the best use of their limited resources, including by adopting reliance mechanisms; be a partner in creating stronger and more resilient regulatory systems, in line with PAHO and WHO recommendations; and continue to implement transparency practices (some examples below).

Examples of practices from industry aligned with GRP principles

- Responsible sharing of clinical trial data in a manner that ensures safeguarding the privacy of patients, clinical investigators and trial participants;
- Routinely collaborating with researchers and providing public access to clinical trial results;
- Supporting national regulatory authorities by providing capacity building training in internationally recognized guidelines and standards;
- Collaborating with regulators in anticipating trends by bringing information related to new technologies and best practices implemented by the regulated sector;
- Providing timely information to and collaborating with regulators on safety and quality issues globally to enable fast regulatory response and decision;
- Engaging in pre submission meetings to proactively deliver information about product development and address any questions from regulators.

Conclusion

FIFARMA deems four priority areas to strengthen Good Regulatory Practices in Latin America and the Caribbean. In line with WHO guidelines and PAHO recommendations and activities to promote the use of GRP, FIFARMA calls for regulatory authorities to set up an overarching dedicated initiative to drive the implementation and adherence of Good Regulatory Practices across all working areas. Ultimately, the adoption of GRP by regulators in Latin America and the Caribbean is fundamental to strengthen regulatory systems, achieve efficiencies, enable regional and international cooperation among agencies and support improved public health outcomes – including the adequate response to unforeseen challenges such as health emergencies. All stakeholders including regulators, industry and academia should continue efforts to fully incorporate principles of GRP, for the highest benefit of patients.