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FIFARMA members represent the innovative pharmaceutical industry and national trade associations in the Latin American Region. FIFARMA is fully supportive the WHO's global 'triple billion' goals¹ 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 the access to high quality pharmaceutical innovations that prolong, preserve and improve life for patients in Latin America.

The Importance of strong regulatory systems in supporting WHO goals

Strong regulatory systems are foundational in delivering these goals. FIFARMA supports the adoption of Good Regulatory Practices² by the Latin America Regulators as a tool to strengthen regulatory systems and thus supporting improved public health outcomes e.g. ensuring that medicinal products and technologies are assessed and approved in a timely and robust manner throughout their life-cycle to benefit the patient.

"Promotion of the adoption of good regulatory practices through internationally-recognized, science-based guidelines, standards and processes for smart regulation as part of the Regulatory action plan 2019-2023"

WHO Delivering Quality-Assured Medical Products for All- 2019-2023. WHO's five-year plan to help build effective and efficient regulatory systems²

"Effective medical product regulations and practices prevent or reduce the likelihood of adverse health outcomes that are associated with products (whether imported or domestic) that are unsafe, substandard and not effective or efficacious."

WHO Global Benchmarking Tool, 2018³

FIFARMA's Assessment and Recommendations on Good Regulatory Practices in the Latin America Region

As the Latin America region evolves towards convergence and capacity building there is a need to strengthen the way the regulators embed the fundamental principles⁴ of Good Regulatory Practices within their organization and activities. FIFARMA recognizes that each country has incorporated these principles to a greater or lesser degree.

FIFARMA sees four key areas of opportunity to strengthen Good Regulatory Practices in the region:

Key areas of opportunity

- ✓ **Embed Transparency** initiatives and principles
- ✓ **Ensure consistency** in the application of regulatory guidances
- ✓ **Embrace Technology** to support Good Regulatory Practices
- ✓ **Support Innovation** driven by Scientific Progress

"The application of the principles of Good Regulatory Practices during the surveillance and the life cycle of the product is encouraged".

**IX PARF- PANDRH
Recommendations⁵**

¹ WHO: Thirteenth general programme of work, 2019–2023

² WHO Good Regulatory Practices (2016): Guidelines for national regulatory authorities for medical products- Draft- Oct 2016

³ WHO Global Benchmarking Tool (GBT) For Evaluation of National Regulatory System of Medical Products- Revision VI, Version1, November 2018

⁴ Legality, Impartiality, Consistency, Proportionality, Flexibility, Effectiveness, Efficiency, Clarity, and Transparency.

⁵PANDRH Conclusiones y adopción de las recomendaciones de la IX CPARF Secretariado Red Parf (OPS/OMS)- Jul2019

FIFARMA calls for Latin America agencies to set up an overarching dedicated initiative to drive the implementation and adherence of Good Regulatory Practices across all working areas.

Some NRA's like CECMED⁶ in Cuba, ISP⁶ in Chile, and ANVISA in Brazil already have existing regulations or agency initiatives that are strengthening their Good Regulatory Practices e.g. performing regulatory impact assessments, extending public consultation periods for regulations to at least 60 days, publication of assessment reports and enabling stakeholder dialogue with the NRA's in preparation for a new regulation and other tools. However, some countries do not have any regulations, working groups, initiatives or entities established to strengthen Good Regulatory Practices.

Who else calls for dedicated Initiatives driving the Implementation of Good Regulatory Practices in Regulatory Agencies?

PAHO in their accreditation process of Reference Agencies recommends the elaboration of a Good Regulatory Practices Manual to achieve appropriate coordination of the normative process and a precise definition of the functions and organizations that participate in it.

OECD, APEC and Mercosur suggest their members improve their regulatory standards, governance and tools (e.g. Regulatory Impact Analysis).

FIFARMA Recommendations for strengthening Good Regulatory Practices in the region

Embed Transparency initiatives and principles

- Transparency is a key principle to embed within NRA's. All stakeholders including patients, payers, the medical community and industry will benefit from transparency initiatives adopted by the NRA's, such as the publication of assessment reports accompanying product approvals.
- Transparently developed regulations fosters trust with stakeholders including patients in the evaluation and approval of medicines. Processes could be refined in the region to include publication of an initial Concept Paper and ensuring sufficient amount of time for comments by the different stakeholders. The WHO recommendation and WTO⁷ agreement of a 60-day commenting period accommodates the need to translate the regulation into other languages to support the commenting process and ensure all interested parties and international stakeholders can provide feedback in a robust manner.
- FIFARMA considers transparency of the products approval process e.g. timelines and the basis of the decision, crucial elements to ensure impartiality to be incorporated by the Latin America regulators. This will increase stakeholder confidence in medicines and other regulated products.

Ensure consistency in the application of regulatory guidances

- As recognized by WHO⁸, consistency in developing, implementing and enforcing regulations is central to good regulatory practices. FIFARMA supports the WHO recommendation that '*new regulations should support and complement, and not conflict with, existing regulations*' and recommends NRA's to identify opportunities to leverage international guidances¹.
- FIFARMA supports the concept that NRA's develop an implementation plan for adopted regulations. We would support working in partnership with NRA's to provide educational seminars and training for impacted stakeholders.

⁶ Manual de Buenas Practicas Regulatorias- 31 Dic 2015, Exenta No. 1067

⁷ WTO- Decisions and Recommendations Adopted by the WTO Committee on Technical Barriers to Trade Since 1 January 1995-G/TBT/1Rev.13- Mar 2017

⁸ WHO Draft Guideline- Good Regulatory practices: guidelines for national regulatory authorities for medical products, Oct 2016

- Implementation of good regulatory practices underpins and facilitates international regulatory cooperation programs, compliance with international treaty obligations and regional agreements. FIFARMA believes that strengthening international regulatory cooperation will benefit the Latin America Region.
- Good Regulatory Practices promote the rationalization of technical requirements which supports convergence, reliance and harmonization activities.

" Promote a change in the regulatory paradigm, building regulatory systems that are solid, efficient and transparent based in concepts such as reliance, work sharing and international cooperation."

IX PANDRH Conference recommendation⁵Error! Marcador no definido.

Embrace Technology to support Good Regulatory Practices

- Technology improvements and digitalization provide an opportunity to support the implementation of mechanisms and embed earlier adoption and monitoring of some aspects of Good Regulatory Practices. Examples include opportunities to strengthen 1) communication with the regulated sector, 2) information sharing, and 3) transparency (e.g. posting the planned regulatory agenda for the following year(s), status of regulations that are in review process, or capturing public comments from the regulated sector).

Support Innovation driven by Scientific Progress

- Good Regulatory Practices supports 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 the 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.

Conclusion

FIFARMA sees four priority areas to strengthen Good Regulatory Practices in the Latin America region. In line with PAHO activities to promote the adoption of these concepts within Regulatory Systems in the region FIFARMA calls for agencies 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 Good Regulatory Practices by the Latin America Regulators is fundamental to strengthen regulatory systems, achieve efficiencies, enable cooperation between agencies and support improved public health outcomes. All stakeholders including regulators, industry and academia should continue efforts to fully incorporate principles in the region for the ultimate benefit of patients.



FIFARMA is the Latin American Federation of the Pharmaceutical Industry created in 1962. We represent 13 research-based biopharmaceutical companies and 9 local associations dedicated to discovering and developing innovative, quality and safe health products and services that improve the lives of patients in Latin America and the Caribbean and advocate for patient-centric, sustainable health systems characterized by high regulatory standards and ethical principles.