Observatory of
Good Regulatory Practices
in the Regulation of Pharmaceutical Products

2024

FIFARMA
FEDERACIÓN LATINOAMERICANA DE LA INDUSTRIA FARMACÉUTICA

INNOS
Instituto de Prospectiva e Innovación en Salud

This report is an independent analysis of the adoption of Good Regulatory Practices (GRP) in pharmaceutical product regulation in eight (8) Latin American countries.

The information comes from reliable sources; however, the data and information described herein will be subject to updates and validation. This study is not an evaluation of the maturity level of national drug regulatory authorities, nor does it substitute or replace official assessments conducted by authorized bodies such as the World Health Organization (WHO) or the Pan American Health Organization (PAHO).

The findings are based on information available at the time of preparation and may be subject to changes.

The study provides an overview of GRP in the analyzed countries and seeks to drive improvements in regulatory matters. The authors and institution assume no responsibility for decisions made based on this report.

Final Report:

Assessment of the Adoption of Good Regulatory Practices in Pharmaceutical Product Regulation in Eight Latin American Countries

2024

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We acknowledge the organizations and individuals who collaborated in the preparation of this report, including representatives from National Regulatory Authorities, the pharmaceutical industry, academics, and other key stakeholders.

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FIFARMA

FIFARMA, the Latin American Federation of the Pharmaceutical Industry, is a non-governmental organization representing the innovative pharmaceutical industry in Latin America and the Caribbean. Its members include leading multinational pharmaceutical companies and trade associations from the region, committed to improving public health through innovation and promoting sustainable healthcare systems.

FIFARMA's main objective is to ensure that patients in Latin America and the Caribbean have timely access to innovative, safe, effective, and high-quality medicines and health technologies. To achieve this, FIFARMA works closely with regional and global stakeholders, developing and implementing policies that promote regulatory harmonization, transparency, and efficiency in healthcare systems.

FIFARMA strongly supports the adoption and implementation of Good Regulatory Practices (GRP) as part of its mission to strengthen regulatory systems in Latin America and the Caribbean. GRP, as recommended by the World Health Organization (WHO) and the Pan American Health Organization (PAHO), are essential for strengthening national regulatory authorities, fostering transparency, consistency, and efficiency in regulatory processes, ensuring that medicines and health products are safe and accessible to those who need them.

The study on GRP implementation in the region is of vital importance, as it highlights key areas where regulatory frameworks can be improved, supporting the convergence of regulatory standards with international best practices. This contributes to making National Regulatory Authorities more resilient and capable of responding to emerging health challenges.

We believe that robust regulatory systems, based on GRP, will improve patient access to life-saving treatments and optimize public health outcomes throughout the region.

FIFARMA is fully committed to supporting the dissemination and adoption of Good Regulatory Practices in Latin America and the Caribbean, and will continue collaborating with Regulatory Authorities, governments, and international organizations to strengthen health systems for the benefit of all Latin American patients.

INNOS

This document from the Observatory of Good Regulatory Practices aims to highlight the importance of adopting the principles and enablers proposed by the World Health Organization (WHO) in the field of pharmaceutical product regulation. These elements are fundamental for developing more efficient, equitable health systems centered on population needs.

In this context, it is essential to emphasize the vital role that the health ecosystem as a whole plays in energizing these regulatory scenarios. Active collaboration between regulatory authorities, academic institutions, pharmaceutical industry, healthcare providers, and civil society is key to promoting access to better health opportunities, improving resolutivity, optimizing timeliness of care, and ultimately achieving positive health outcomes for our populations.

This initiative is carried out as an integral part of the activities of the Health Think Tank -INNOS-, an initiative whose primary objective is to strengthen healthcare industry frameworks. Through this effort, INNOS seeks to generate better processes for connection, development, research, and innovation in the health sector, thus contributing to the evolution and continuous improvement of health systems in the Latin American region.

In the following pages, we will explore in detail how the adoption of good regulatory practices, aligned with WHO principles and enhanced by a collaborative health ecosystem, can positively transform the health reality of our countries, promoting more equitable and efficient access to quality health services.

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1. Executive Summary

Study Objective

To evaluate the state of adoption of Good Regulatory Practices (GRP) in the regulation of pharmaceutical products in eight Latin American countries: Argentina, Brazil, Chile, Colombia, Costa Rica, Ecuador, Mexico, and Peru.

Context

GRPs represent a set of principles and practices applied to improve the quality of regulation and achievement of expected outcomes. The World Health Organization (WHO) and the Pan American Health Organization (PAHO) recognize the value of GRPs, inviting member states to integrate GRP principles into their regulatory systems and consider establishing roadmaps, after consultation with stakeholders, to monitor progress in their implementation.

The ability to demonstrate consistent adherence to GRP principles is also a key part of the Regulatory Performance Assessment Process (PEP) that WHO uses to define World Listed Authorities (WLA), and is therefore considered a hallmark of any trusted regulator.

Methodology

Opinions were collected from professionals working in National Regulatory Authorities for Medicines (NRAs), pharmaceutical laboratories, and consulting firms that advise the industry on NRA procedures, and a comprehensive analysis was conducted of regulatory frameworks, institutional capacity, and country-specific challenges related to GRP using available bibliographic references on Regulatory Systems practices.

Study Overview

This first edition of the study evaluates the adoption of GRPs in pharmaceutical product regulation in eight Latin American countries: Argentina, Brazil, Chile, Colombia, Costa Rica, Ecuador, Mexico, and Peru. The analysis focuses on WHO Annex 11 recommendations, examining regulatory frameworks, institutional capacity, and country-specific challenges.

The study aims to identify strengths and opportunities for improvement that contribute to more effective and uniform adoption of GRPs, with the goal of strengthening regulatory systems through efficient processes that ensure timely access and continuity in the supply of therapies for patients.

Key Findings

- Significant disparities in GRP adoption among the studied countries.
- Some countries have achieved notable progress, while others face challenges in regulatory infrastructure and technical capacity.
- Urgent need for greater regulatory harmonization and convergence and increased international regulatory cooperation.

Expected Impact

Strengthen regulatory systems to improve the evaluation of pharmaceutical products, thus promoting timely access to them, increasing confidence in these systems, and developing capabilities to face future public health challenges.

Conclusion

The region shows diverse progress in the adoption of Good Regulatory Practices for Pharmaceutical Products (GRPPP), without cases of significant lag or exceptional advances. WHO principles and enablers provide a valuable guiding framework for aligning efforts. Progress is driven by collaborative work between authorities and stakeholders, as well as technology adoption. However, authority funding remains a critical aspect in the region that requires attention to continue progress in GRPPP implementation.

Key Recommendations

- Strengthen the commitment of all stakeholders in supporting the adoption of GRPs in Pharmaceutical Product Regulation, as well as their principles and enablers.
- Promote socialization and develop collaborative initiatives focused on less implemented aspects, thus facilitating the exchange of progress and experiences.

1. Resources and Capabilities

- Strengthen and diversify Authority funding mechanisms.
- Investment in technological infrastructure to improve efficiency.
- Implementation of robust quality management systems.

2. Networks and Collaboration

- Strengthening of the Pan American Network for Drug Regulatory Harmonization (PANDRH Network).
- Promotion of intersectoral collaboration between agencies, industry, academia, and patient organizations.
- Creation of multinational thematic working groups.

3. Dynamics

- Harmonization of regulatory frameworks with international standards.
- Promotion of transparency through information access policies.
- Establishment of “Regulatory Reliance” mechanisms.

2. Introduction

According to WHO data, more than two billion people lack access to essential pharmaceutical products, a situation that particularly affects developing countries where regulatory barriers are one of the factors limiting the availability of safe and effective treatments.

Regulatory systems play a crucial role in ensuring the safety and efficacy of pharmaceutical products, but they are also a vital component in fostering health innovation and improving public health outcomes. The region needs to improve its regulatory capabilities and strengthen cooperation between regulatory authorities to enhance access to innovative products, which impacts the wellbeing of millions of inhabitants.

To address these challenges, the World Health Organization -WHO- has developed tools such as the Global Benchmarking Tool -GBT-, which allows for the assessment of national regulatory systems' maturity. This tool classifies systems into four levels, from the absence of a formal framework -Level 1- to an advanced system with continuous improvement -Level 4-. The goal is for countries to reach at least Level 3, ensuring robust regulatory systems that guarantee pharmaceutical product safety and facilitate access.

In this context, GRPs are fundamental for advancing toward regulatory maturity. These practices include principles such as transparency, coherence, and predictability in pharmaceutical product regulation. Evaluating the adoption of these principles is essential to strengthen the region's regulatory frameworks, ensure more equitable access to pharmaceutical products, and accelerate the introduction of technological innovations.

The COVID-19 pandemic exposed both the strengths and weaknesses of regulatory systems in Latin America. The need for agile responses and risk-based approval procedures became evident, and the lack of harmonization between countries highlighted the urgency of adopting GRPs at a regional level.

In the post-pandemic scenario, the region's health systems face additional challenges regarding equitable access, financial sustainability, and innovation capacity. Regulatory authorities have the responsibility not only to ensure the safety and efficacy of pharmaceutical products but also to accelerate their availability without compromising quality. This is where GRPs play a decisive role.

The comprehensive analysis of each country identifies strengths and areas for improvement, providing a detailed overview of GRP implementation and opportunities for more effective adoption in the region. It is essential that all actors in the health ecosystem – Regulatory Authorities, pharmaceutical industry, governments, and civil society – work in alignment to implement these practices. The coherent and effective adoption of GRPs will enable the region's health systems to improve access to healthcare innovations, respond agilely to public health emergencies, and ensure long-term sustainability.

The report's structure is designed to offer a comprehensive view of the current state and regulatory challenges of the 8 Latin American countries. It begins with a theoretical framework that delves into GRPs and their alignment with WHO and PAHO guidelines. Then, it describes the methodology used to evaluate the implementation of these practices in the studied countries, detailing the evaluation tools and criteria. The results include an analysis of GRP adoption, highlighting strengths and areas for improvement. The report presents specific recommendations to enhance regulatory frameworks and progress toward more efficient and harmonized systems, aligned with the objectives of accessibility, innovation, and sustainability of health systems in the region. Finally, it concludes with the presentation of bibliographic references.

This approach ensures that the report is not only an assessment of the current state but also a practical guide for the continuous improvement of pharmaceutical product regulation.

3. Theoretical and Reference Framework

3.1 Definition of Good Regulatory Practices

GRPs are a set of principles, policies, and practices that guide regulatory authorities in the development, implementation, and review of regulations in an effective, coherent, transparent, and science-based manner. These practices aim to ensure that regulatory decisions are fair, proportional, and predictable, promoting public health and the safety of pharmaceutical and other medical products.

In the Latin American context, GRPs are fundamental to strengthen countries' regulatory capacity and ensure that pharmaceutical product regulation aligns with international standards. The adoption of GRPs by regulatory authorities and other key stakeholders, such as the pharmaceutical and health innovation industry, is essential to improve regulation quality, foster public trust, and facilitate international harmonization and cooperation. (WHO, 2022)

3.2 GRP Principles according to WHO

The World Health Organization (WHO) has established a comprehensive framework for GRPs, outlined in Annex 11 of its Technical Report Series. This framework includes nine fundamental principles that should guide the work of regulatory authorities, and which are equally applicable in the Latin American context *(WHO, 2022)*:

Legalidad

Regulatory systems and decisions derived from them must have a solid legal foundation.

Consistency

Regulatory oversight of pharmaceutical products should be consistent with existing government policies and legislation and be applied uniformly and predictably.

Independence

Institutions in charge of pharmaceutical product regulation must be independent.

Impartiality

All regulated parties must receive equitable, fair, and impartial treatment.

Proportionality

Regulation and regulatory decisions must be proportional to the risk and the regulator's capacity to implement and enforce them.

Flexibility

Regulatory oversight should not be prescriptive but flexible to respond to a changing environment and unforeseen circumstances. Timely responsiveness to specific needs and especially public health emergencies must be integrated into the regulatory system.

Clarity

Regulatory requirements must be accessible to users and understood by them.

Efficiency

Regulatory systems must achieve their objectives within the required timeframe and with reasonable effort and cost. International collaboration promotes efficiency by ensuring the best use of resources.

Transparency

Regulatory systems must be transparent, requirements and decisions must be disclosed, and input must be sought on regulatory proposals.

These principles are essential to ensure that Regulatory Authorities in Latin America can fulfill their mandate to protect public health while facilitating access to safe and effective medicines.

3.3 Enabling elements of good regulatory practices

GRP enabling elements **are essential components that create an enabling environment for the effective implementation of regulations in the health sector.** These elements range from political support to human and financial resources, including quality management systems and evidence-based decision-making processes. The following key elements that contribute to the success of a solid and efficient regulatory framework are detailed below *(WHO, 2022):*

Political and whole-of-government support

Sustained support from the highest political and governmental levels, including policymakers, is paramount for the proper application of good regulatory practice concepts and principles.

These good practices must be an integral part of all government policies on regulatory systems and have strong political support.

Robust quality management system

A quality management system, which includes the application of quality risk management principles, makes regulatory authority decisions more credible and their operations more stable and consistent. A quality management system contributes to systematic planning, control, and quality improvement across all regulatory function processes and ensures a comprehensive approach.

Communication, collaboration, and coordination

Adequate and effective communication plays a fundamental role in information exchange within and outside the institutions that constitute the regulatory system. When regulatory authorities communicate regularly, both internally and externally, they remain more transparent and accountable. Communicating correct information prevents potential misunderstandings and the spread of misleading information to patients and the public. Communication is a powerful tool for collaboration and coordination with relevant national and international stakeholders, which in turn leads to efficient use of resources and better regulatory outcomes.

Given their responsibilities, regulatory authorities must have adequate staff, infrastructure, and technical tools to perform their tasks. Coordination can be facilitated by communication technologies and efficient and rapid information exchange, resulting in fewer gaps and less duplication of efforts.

Science and data-based decision-making process

Regulatory decisions and decision-making must be based on scientific foundations and accurate data rather than intuition or arbitrariness. Science-based decisions provide consistent and predictable regulatory outcomes. Adherence to international standards and guidelines is a primary enabling element in science-based regulatory decision-making.

The enabling elements listed above are not effective when present individually. On the contrary, these factors work in harmony in the application of good regulatory practices. For example, sufficient and sustainable financial resources contribute to the recruitment, development, and maintenance of competent human resources. Likewise, financial resources must be managed in accordance with good governance practices.

Sufficient and sustainable financial resources

Investment in a regulatory system is fundamental to the proper functioning of a healthcare system. Having sufficient financial resources to effectively fulfill its regulatory mandate and continuously improve the performance of regulatory activities is fundamental to the independence, impartiality, consistency, and efficiency of a regulatory system. The financial resources of all institutions in the regulatory system must be sustainable, apart from contributions from donors or philanthropic entities.

Effective organization and good governance

The structure and line of authority among all institutions in the regulatory system and within each of them must be well defined.
The integrity of the overall regulatory system is fundamental to the efficient performance of each of its constituent institutions. If more than one institution participates in the regulatory system, institutional legislation or regulation must provide for clear coordination without overlap of regulatory activities. Leadership is fundamental to establishing and realizing the organization's vision, mission, policies, and strategies, which in turn contribute significantly to its efficiency.

Ethics and institutional values

Regulatory staff must comply with the institution's ethical principles and values and demonstrate professionalism. All regulatory staff must know and receive training on the regulatory authority's ethical principles and values (for example, a code of conduct). A system must be established, within or outside the regulatory system, to manage deviations from ethics and institutional values.

Competent human resources

A range of technical and scientific knowledge and skills of regulatory staff contribute to the development, implementation, and maintenance of an effective regulatory system for medical products.

Personal and professional promotion policies and measures (for example, training programs, competitive remuneration schemes) are fundamental for regulatory authorities to attract and retain competent staff in service.

3.4 Comparison with regional and global guidelines (ASEAN, FDA, etc.)

The WHO GRP framework aligns and complements other international and regional guidelines, such as those established by ASEAN and the U.S. FDA. These comparisons are relevant for Latin America in its effort to strengthen its regulatory systems and align its practices with international standards.

ASEAN: The Association of Southeast Asian Nations (ASEAN) has developed its own GRP guidelines, which emphasize the importance of regional coherence and cooperation to ensure that regulations are effective and harmonized throughout the region. These guidelines also underscore the importance of transparency, public consultation, and regulatory impact assessment, principles that are equally applicable and beneficial for Latin America.

FDA (Estados Unidos): The FDA has been a leader in GRP implementation, with a particular focus on transparency and accountability through initiatives such as FDA-TRACK. FDA guidelines emphasize the importance of public consultation, information disclosure, and efficiency in regulatory processes, elements that can serve as benchmarks for improving regulatory practices in Latin America.

Comparing these guidelines with WHO recommendations allows for identifying key similarities and differences, and provides a broader context for understanding how GRPs are implemented in different regulatory environments. Additionally, these comparisons help highlight best practices that could be adopted by Latin American countries to strengthen their regulatory frameworks and improve international cooperation.

3.5 Analysis of WHO and PAHO guidelines on GRP

Both the **WHO** and the **Pan American Health Organization (PAHO)** have developed specific guidelines to support GRP implementation in member countries, including those in Latin America. These guidelines recognize that effective adoption of **GRP** is fundamental to strengthening regulatory systems and ensuring that pharmaceutical products available in the market meet safety, efficacy, and quality standards.

WHO's **Annex 11** provides a detailed framework that describes best regulatory practices and how they should be implemented to maximize their impact on public health. This framework includes recommendations for creating clear policies, training competent personnel, transparency in decision-making, and international cooperation, all essential for Latin American countries.

PAHO, for its part, has promoted the use of these guidelines through workshops, seminars, and institutional strengthening programs in the Americas region. In Latin America, these efforts have been key to adapting GRP to each country's specific needs and promoting regulatory harmonization in the region. However, the region lacked an assessment of the adoption of these principles and enablers, which led to the creation of the **Good Regulatory Practices Observatory for pharmaceutical product regulation**. Below is the methodology we adopted to conduct this first assessment and establish the baseline for this observatory.

4. Objective and Justification of the Observatory

The **Good Regulatory Practices Observatory (GRPO)** aims to strengthen the regulatory capacity of Latin American countries by providing insight into the implementation of GRP in pharmaceutical product regulation, following WHO Annex 11 recommendations. This framework promotes transparent, coherent, and science-based practices that are key to ensuring the safety, efficacy, and quality of pharmaceutical products. The main objective of the observatory is to support regional regulatory authorities in adopting these GRP, creating a regulatory environment that effectively addresses current and future challenges in Latin American health systems.

The creation of the GRPO responds to the need for information about GRP adoption levels across different countries, enabling governments to make informed decisions to strengthen regulatory systems in line with international standards and WHO recommendations, while fostering health innovation and accelerating access to medical technologies. Given the disparity in infrastructure, funding, and technical capacity among countries, the GRPO seeks to provide elements to **harmonize regulatory practices and promote regional collaboration**, thus strengthening health systems and ensuring equitable access to quality pharmaceutical products.

The GRPO's mission is to monitor GRP adoption and provide practical tools and relevant data to Regulatory Authorities and decision-makers. WHO Annex 11 provides clear guidance on how regulatory systems should be structured and operated, emphasizing transparency, independence, and consistency in pharmaceutical product approval processes. **By following these recommendations, the observatory aims for countries in the region to adopt a regulatory approach that not only ensures pharmaceutical product quality but also facilitates access to technological innovations,** vital for improving health systems.

A **solid and harmonized regulatory framework** is fundamental to addressing public health challenges, such as equitable access to pharmaceutical products, health system sustainability, and response capacity for future emergencies. Through the GRPO, the goal is to **promote a culture of better regulatory practices** that strengthens health systems in Latin America. Additionally, the observatory seeks to increase public trust in regulatory systems and pharmaceutical product safety, as well as foster collaboration between public and private sectors.

The **expected benefits** of GRP adoption and monitoring include strengthening **regulatory capacity** to develop more effective and transparent frameworks, increasing confidence in regulatory systems, and creating a favorable environment for health innovation. Furthermore, it will facilitate **access to innovative pharmaceutical products, accelerating the arrival of new technologies to** patients, and will drive **regional regulatory harmonization**, promoting cooperation between countries under common standards based on WHO recommendations, and improving the maturity level of regulatory authorities.

This report seeks to provide a comprehensive assessment of the current state of GRP adoption in pharmaceutical product regulation in eight Latin American countries: **Argentina, Brazil, Chile, Colombia, Costa Rica, Ecuador, Mexico, and Peru.** The analysis identifies strengths and areas for improvement in GRP implementation, offering practical recommendations for decision-makers and regulatory authorities to optimize their regulatory frameworks, aligning with international standards.

5. Methodology

5.1 Description of Data Collection Process

The study methodology was based on World Health Organization (WHO) Annex 11 on GRP in pharmaceutical product regulation. A structured survey was designed based on the key elements of each principle and enabler established by WHO, using a rubric (descriptive statement) that aligns the ideal state of each element with WHO standards.

The survey rubric includes three levels of adoption of principles and enablers, defined as follows:

No opinion

Basic
Initial adoption phase with partial implementation.

Intermediate:
Significant progress with established processes, but with areas for improvement.

Advanced:
Principle fully integrated and consistently applied.

Additionally, an online survey system was used, with objective language adapted to regulatory system stakeholders.

- Scoring System

The evaluation was conducted on a scale of 0 to 100 points, where 100 represents the maximum score. The levels were scored as follows:

- Basic: 1 point.
- Intermediate: 2 points.
- Advanced: 3 points.

Responses marked as "No Opinion" were not considered in the scoring. The sum of the scores obtained generated an overall rating from 0 to 100, which is expressed in the graphs as a percentage.

5.2 Information Sources

For the preparation, analysis, and recommendations of this report, information sources included:

- Structured survey (primary source) and assessment of general perception of GRP adoption.
- Official Regulatory Authority documents
- International organization reports (WHO, PAHO).
- Academic publications on pharmaceutical product regulation.
- International and regional databases.

5.3 Methodological Tools

The following tools were used:

- Structured survey and assessment of general perception of GRP adoption.
- Document analysis tools.
- Statistical analysis tools.
- Content analysis software for open-ended responses.

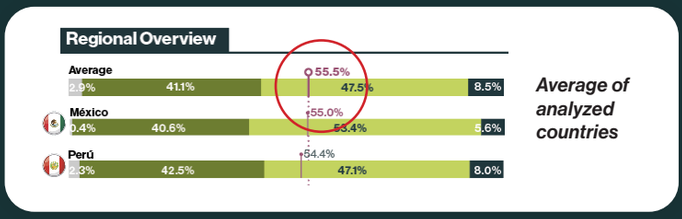
5.4 Country and Regulatory Agency Selection Criteria

Eight key countries were selected: Argentina, Brazil, Chile, Colombia, Costa Rica, Ecuador, Mexico, and Peru, based on their geographic diversity, pharmaceutical market size, level of economic development, and maturity of their regulatory systems. The influence of the Regulatory Authorities of these eight countries is central to the implementation of GRP throughout the region and their influence on regional harmonization.

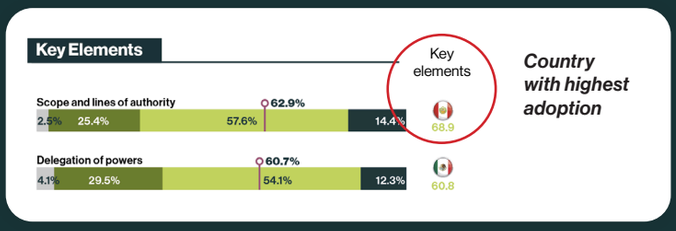
6. Study Results

This chapter presents the results of the analyzed countries, including: Percentages by different categories:

- **Basic, intermediate, advanced and no opinion.**
- Total percentage of principle adoption.



- Percentages by different categories: basic, intermediate, advanced and no opinion.
- Country with highest component adoption.



6.1 Introduction: General Results of Received Surveys

The survey results on GRP general principles reveal significant variability among the studied countries. It is important to note that data collected from Brazil, Argentina, Chile, and Ecuador is not significant due to low response rates, therefore the analysis primarily focuses on Colombia, Costa Rica, Mexico, and Peru. Focusing on these countries, we observe that the Legality principle shows relatively consistent implementation, with intermediate to advanced levels. However, other principles such as Consistency, Independence, Impartiality, Proportionality, Flexibility, Clarity, Efficiency, and Transparency show greater variation. The study reveals disparities in GRP adoption progress among Colombia, Peru, Mexico, and Costa Rica. There is clear evidence of the need to strengthen institutional and technical capacities to achieve a more comprehensive implementation of GRP in these countries.

Total Number of Surveys Received (240)

This section presents a detailed breakdown of the total number of surveys received, providing an overview of response distribution by country. This quantitative analysis is fundamental to understanding the representativeness of the data collected in each market and to contextualize the subsequent results.

México	Colombia	Costa Rica	Perú	Argentina	Chile	Ecuador	Brasil
32.5%	**24.6%**	**12.5%**	**12.1%**	**6.3%**	**5.8%**	**4.6%**	**1.7%**

Total surveys received: 100%

Participating Groups

The survey received responses from various groups within the pharmaceutical sector from 8 Latin American countries. Multinational pharmaceutical laboratories constituted the majority of participants, representing **65%** of the total. Regulatory service consultants formed the second largest group with **14.6%**, followed by national pharmaceutical laboratories with **7.1%.** National Regulatory Authorities represented **2.1%** of responses. This distribution provides a perspective consistent with the regulatory landscape and its stakeholders in the region.

240
Participants from 8 Latin American countries

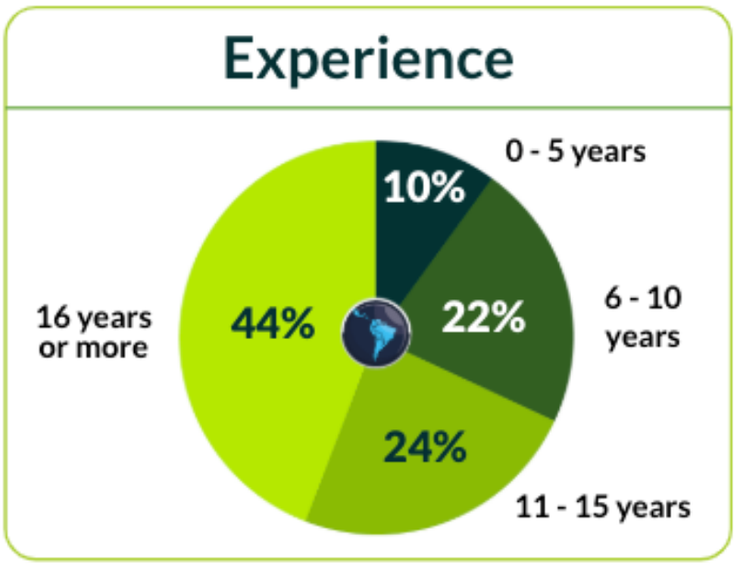
Stakeholder Groups

- National pharmaceutical laboratories
- Multinational pharmaceutical laboratories
- Regulatory service consultants
- National regulatory authority officials
- Other

Descriptive Data of the Participating Population

The descriptive data of the survey respondent population reveals a varied distribution in terms of experience and areas of specialization. The majority of participants **44%** have 16 or more years of experience in the sector, suggesting a high level of knowledge. Regarding areas of expertise, Regulatory Affairs dominates with **45.5%** of respondents, followed by Pharmacovigilance with **19.5%.**

This combination of extensive experience and specialization in key areas provides a solid foundation for the assessment of GRP in the region.



6.2

Principles

Regulatory principles are fundamental for establishing a solid and efficient framework in pharmaceutical product regulation. These principles, which include legality, consistency, independence, impartiality, proportionality, flexibility, clarity, efficiency, and transparency, are essential to ensure that regulatory systems are fair, transparent, and effective.

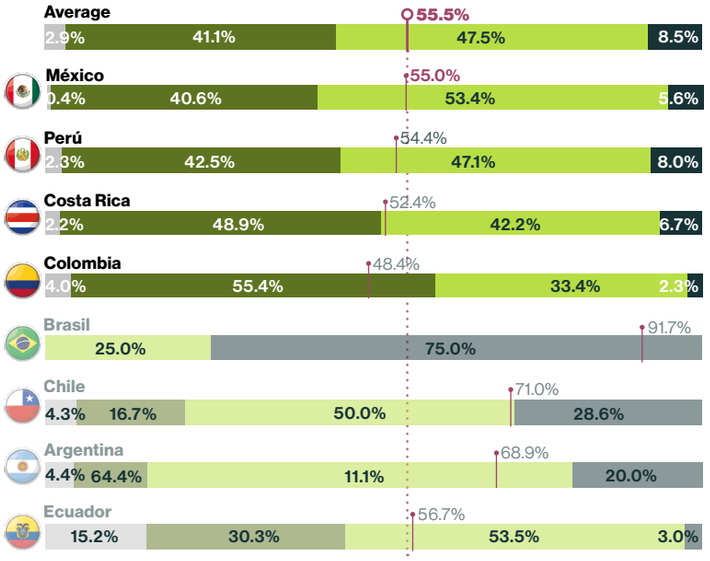
In this study, we evaluate the adoption of these principles in the selected countries.

Below are the results of the study conducted and broken down by principle.

Legality

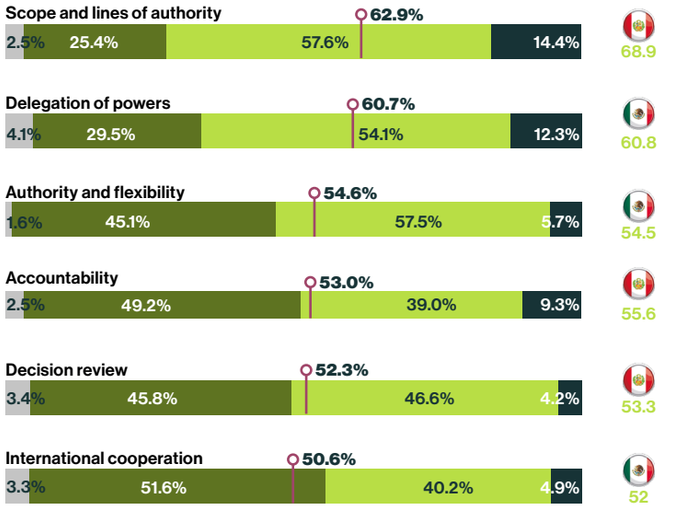
Regulatory systems and the decisions derived from them must have a solid legal foundation. *(WHO. 2022.)*

Regional Overview



Graph 1.

Key Elements



Graph 2.

No opinion *Basic* *Intermediate* *Advanced* *Average*

The average for the legality principle *(Graph 1)* stands at an intermediate level of 55.5. This result reflects moderate progress in adopting solid legal frameworks for pharmaceutical regulation in the region. The graph shows variability among the analyzed countries, with Colombia, Costa Rica, Mexico, and Peru showing scores ranging between 48.4 and 55.0.

The key elements with the best adoption are "Scope and Lines of Authority" and "Delegation of Powers," with higher intermediate and advanced levels *(Graph 2).* The key elements showing the greatest lag are "International Cooperation" and "Decision Review." These results demonstrate that, although there is room for improvement, solid foundations exist in the region to continue strengthening legal frameworks in pharmaceutical regulation.

Strengths:

The principle of legality shows significant strengths in two Latin American countries, which are presented below:

- **Perú:** A reference in "Scope and Lines of Authority" and "Accountability," suggesting it has a well-defined regulatory structure and indicates a commitment to transparency.
- **México:** Stands out in "Delegation of Powers" and "International Cooperation," indicating it has a clear distribution of responsibilities and, additionally, shows willingness to collaborate with other countries.

Areas for Improvement:

The analysis reveals areas with the greatest gaps in the application of the legality principle in the region, presenting significant opportunities for improvement, such as:

- **Authority and Flexibility:** Current regulatory frameworks show limitations in their robustness and adaptability to the changing dynamics of the pharmaceutical sector.
- **Decision Review:** There is a lack of robustness and transparency in regulatory decision appeal and review processes.
- **International Cooperation:** Collaboration between countries for the harmonization of regulatory practices and standards shows notable deficiencies.
- **Accountability:** Existing mechanisms for transparency and responsibility in regulatory processes.

Strengthening these areas could lead to substantial improvement in the effectiveness and reliability of regulatory systems in the region.

Reference to Consider (Good Practices from Other Countries):

The FDA is a global reference in pharmaceutical regulation, distinguished by its rigorous regulatory framework, transparency, and scientific approach. The FDA provides clear guidance to industry, contributing to a predictable and coherent regulatory environment. (Source: Food and Drug Administration. (2023). What We Do.)

Recommendations

Based on the analysis of the legality principle, it is recommended to:

- Establish regulatory agendas with a defined program for reviewing and updating regulations, standards, and processes.
- Implement clear procedures and consultation mechanisms that ensure uniform and traceable application of these procedures.
- Implement public information systems that allow tracking of regulatory decisions and encourage participation from all stakeholders.Develop continuous training programs for regulatory personnel, focused on consistent application of regulations and adoption of international best practices.- Establish clear and efficient mechanisms for reviewing and appealing regulatory decisions, ensuring a fair and transparent process.
- Foster international and regional cooperation in regulatory matters.
- Implement systems for continuous evaluation and monitoring of regulatory framework effectiveness, allowing for evidence-based adjustments and improvements.

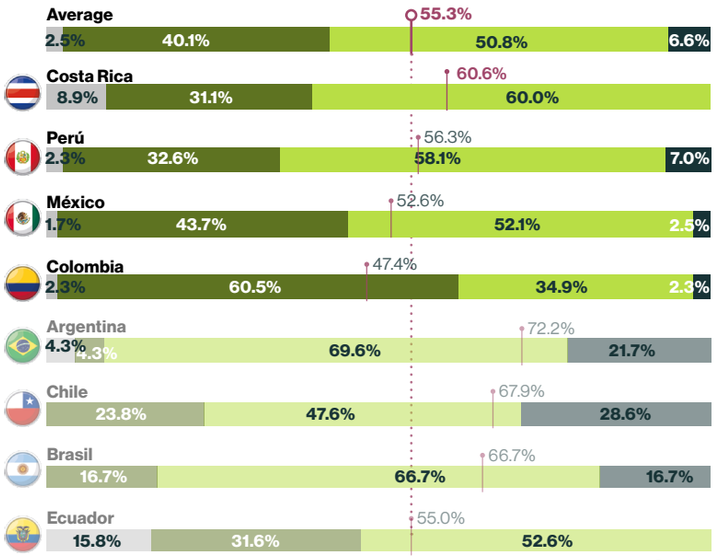
The implementation of these recommendations will contribute to improving the quality, consistency, and effectiveness of regulatory frameworks, fostering an environment more conducive to innovation and access to safe and effective medicines.

This document does not include data from the following countries: Brazil, Argentina, Chile, and Ecuador due to low representativeness in the responses to the instrument used in the study.

Coherence

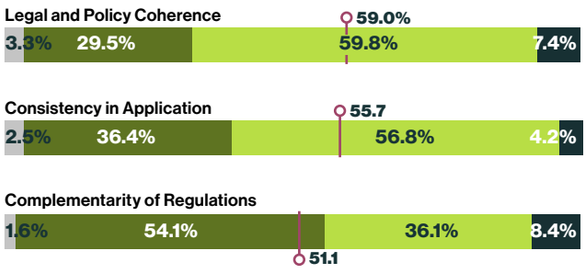
Medical product regulatory oversight should be coherent with existing government policies and legislation and should be applied in a homogeneous and predictable manner. *(WHO.2022)*

Regional Overview



Graph 3.

Key Elements



Graph 4.

No opinion *Basic* *Intermediate* *Advanced* *Average*

The average for the coherence principle *(Graph 3)* stands at a medium level with **55.3.** This result indicates moderate progress in the coherent application of policies and legislation in pharmaceutical product regulation in the region. The graph shows variability among the analyzed countries, with scores ranging between **47.4** and **60.6** for Colombia, Costa Rica, Mexico, and Peru. Colombia presents the lowest score at **47.4**, while Costa Rica shows the highest at **60.6** among these countries, reflecting differences in the homogeneity and predictability of their regulatory systems.

The key elements "Legal and Policy Coherence" and "Consistency in Application" show the highest levels of adoption *(Graph 4)*. "Complementarity of Regulations" shows the greatest lag. This disparity suggests the need for a balanced approach to improve overall regulatory coherence in the region's pharmaceutical product sector. *(Graph 4)*

Strengths:

The principle of coherence shows significant strengths in two Latin American countries, which are presented below:

- **Costa Rica:** Stands out in "Consistency in Application," suggesting uniform and predictable application of regulations.
- **Perú:** Excels in "Legal and Policy Coherence" and "Complementarity of Regulations," indicating strong alignment between existing policies and legislation.

Areas for Improvement:

Despite advances in regulatory coherence, opportunities for improvement are identified in the following area:

- **Complementarity of Regulations:** This key element shows the lowest scores, indicating the need to improve integration and harmonization between different regulations in the pharmaceutical product sector.
- **Consistency in Application:** Although it shows better results than the previous key element, there is still room to perfect uniformity in the application of regulations over time and across different cases.

Addressing these areas will improve the predictability and effectiveness of the regulatory framework, benefiting both industry and patients in the region.

Reference to Consider (Good Practices from Other Countries):

The United States Food and Drug Administration (FDA) is a global reference in regulatory coherence. The FDA implements a uniform approach in the evaluation and approval of medicines, ensuring consistency in its decisions across different product categories. Its centralized review system and detailed industry guidelines promote predictability and transparency in the regulatory process *(Source: U.S. Food and Drug Administration, 2024 https://www.fda.gov/about-fda.)*

Recommendations

Based on feedback received from participants and the analysis conducted, the following recommendations are proposed to improve regulatory coherence in the region:

- Strengthen interinstitutional coordination: Establish formal mechanisms for communication and collaboration between different regulatory agencies and ministries involved in pharmaceutical product regulation to ensure coherence in policies and their implementation.
- Implement a periodic review system: Develop a systematic process to evaluate and update existing regulations, ensuring alignment with scientific advances and international best practices.
- Harmonize regional regulations: Foster collaboration among Latin American countries to establish common standards and harmonized regulatory processes, thus facilitating regulatory coherence at the regional level.
- Improve transparency and communication: Establish clear and accessible communication channels to inform all stakeholders about regulatory changes and their justification, thus promoting understanding and compliance with regulations.
- Continuous training: Implement training programs for regulatory officials, ensuring consistent interpretation and application of regulations at all levels of administration.
- Adopt a risk-based approach: Develop and implement a regulatory framework that prioritizes resources and efforts in areas of greatest risk to public health, ensuring more efficient and coherent regulation.

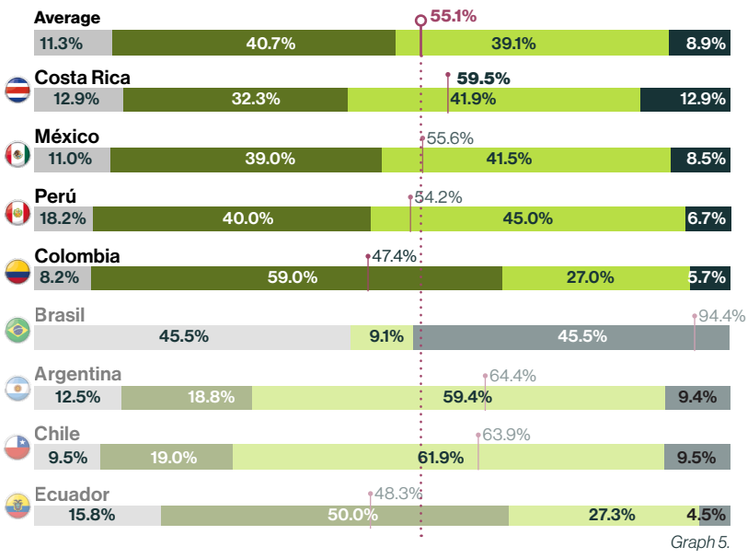
The implementation of these recommendations will contribute to improving regulatory coherence in the pharmaceutical product sector, promoting a more predictable, efficient, and favorable regulatory environment for innovation and access to quality pharmaceutical products.

This document does not include data from the following countries: Brazil, Argentina, Chile, and Ecuador due to low representativeness in the responses to the instrument used in the study.

Independence

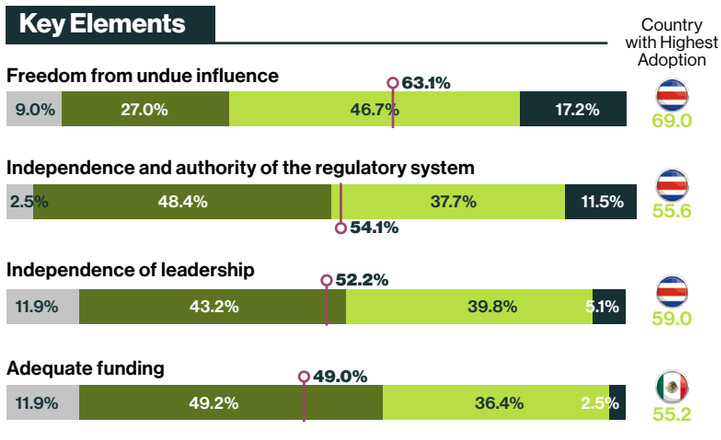
Medical product regulatory institutions must be independent *(OMS.2022)*.

Regional Overview



Graph 5.

Key Elements



Graph 6.

No opinion *Basic* *Intermediate* *Advanced* *Average*

The average for the independence principle *(Graph 5)* stands at a **medium level of 55.1**. This result suggests moderate progress in the autonomy of pharmaceutical product regulatory institutions in the region. The graph shows variability among the analyzed countries, with scores ranging between **47.4 and 59.5** for Colombia, Costa Rica, Mexico, and Peru. Colombia presents the **lowest score at 47.4**, while Costa Rica shows the highest at **59.5** among these countries, indicating differences in the degree of independence of their regulatory systems.

The key elements "Freedom from Undue Influence" and "Independence and Authority of the Regulatory System" show the best adoption, with medium and advanced levels *(Graph 6)*. However, "Adequate Funding" and "Independence of Leadership" show greater lag. These results indicate that, although there are significant advances in some areas of regulatory independence in the region, important challenges persist in terms of funding and independent leadership.

Strengths:

The principle of independence shows significant strengths in two Latin American countries, which are presented below:

Costa Rica stands out in several key elements:

- "Freedom from Undue Influence": Obtains the highest score, indicating a strong commitment to integrity and transparency in regulatory processes.
- "Independence and Authority of the Regulatory System": Leads in this category, suggesting a regulatory structure with greater autonomy in decision-making.
- "Independence of Leadership": Stands out with the highest score, pointing to greater autonomy in the leadership of regulatory institutions.

México: Shows the best performance in "Adequate Funding" (55.2%), implying a more solid financial base to maintain the independence of the regulatory system.

Areas for Improvement:

Despite the advances observed in some areas of regulatory independence in the region, there are significant opportunities for improvement in certain categories:

- **Adequate Funding:** shows significant lag, indicating the need to strengthen funding mechanisms to ensure the operational autonomy of regulatory agencies.
- **Independence of Leadership:** presents challenges in several countries, suggesting the importance of implementing more robust processes for the selection and protection of regulatory leaders against external influences.

Addressing these areas of opportunity could significantly contribute to raising the overall level of independence in the region's regulatory systems, bringing them closer to international best practices.

Reference to Consider (Good Practices from Other Countries):

The European Medicines Agency (EMA) stands out as a global reference in regulatory independence in the pharmaceutical sector. The EMA operates under a robust legal framework that guarantees its autonomy, with a governance system that includes an independent Management Board and scientific committees composed of experts from across Europe. Its funding model, which combines EU funds with industry fees, is designed to maintain its impartiality. Additionally, the EMA implements strict conflict of interest management and transparency policies, which are considered global best practices. (Source: European Medicines Agency. (2023). Governance documents. https://www.ema.europa.eu/en/about-us/how-we-work/governance-documents.)

Recommendations

Based on feedback received from participants and the analysis conducted, the following recommendations are proposed to improve regulatory independence in the region:

- Ensure capabilities, knowledge, skills, and competencies in Authority officials and leaders: Focus on developing a highly qualified and autonomous body of professionals capable of making regulatory decisions based on scientific evidence.
- Public evaluation and accountability of leadership performance: Implement a transparent evaluation system that ensures the independence of regulatory leaders, measuring their ability to maintain integrity and autonomy in their decisions against political or commercial pressures.
- Recognition mechanisms for leadership performance: Establish incentives that reward the demonstration of independence in regulatory decision-making, fostering a culture of integrity and autonomy at all levels of the regulatory authority.
- Strengthen funding for regulatory operation and improvement: Ensure a diversified and stable funding base that allows regulatory agencies to operate with financial autonomy, reducing dependence on single sources that could compromise their independence.

These recommendations seek to address the areas of opportunity identified in the analysis, with the objective of raising the overall level of independence in the region's regulatory systems, bringing them closer to international best practices.

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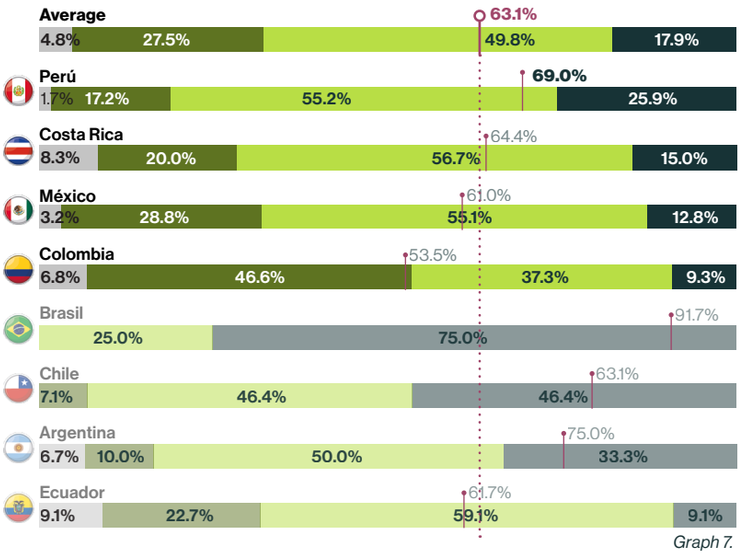
Impartiality

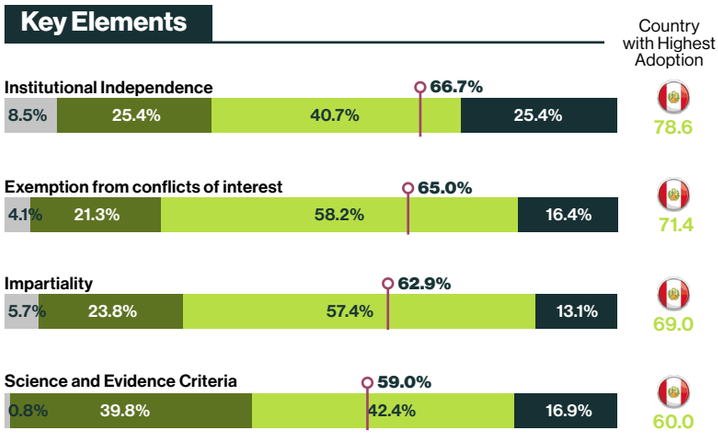
All regulated parties must receive equitable, fair, and impartial treatment *(WHO.2022)*.

Regional Overview



Graph 7.

Key Elements



Graph 8.

No opinion *Basic* *Intermediate* *Advanced* *Average*

The average for the impartiality principle *(Graph 7)* stands at a **medium level of 63.1**. This result indicates significant progress in implementing impartial practices in pharmaceutical regulation across the region. The graph shows variability among the analyzed countries, with scores ranging between **53.5 and 69.0** for Colombia, Costa Rica, Mexico, and Peru, reflecting different degrees of progress in adopting this fundamental principle.

The key elements with the best adoption are "Exemption from Conflicts of Interest" and "Institutional Independence," with higher medium and advanced levels *(Graph 8)*. The key elements showing the greatest lag are "Impartiality" and "Science and Evidence Criteria." These results indicate that, although there are significant advances in some areas of impartiality in the region, important challenges persist in terms of institutional independence and the use of scientific criteria in regulatory decision-making.

Strengths:

The principle of impartiality shows significant strengths in Peru, which are presented below:

- "Exemption from Conflicts of Interest": Reflects a solid commitment to integrity in regulatory processes.
- "Impartiality": Demonstrates a balanced approach to regulatory decision-making.
- "Institutional Independence": Indicates significant autonomy of its regulatory agencies.
- "Science and Evidence Criteria": A strong emphasis on decisions based on scientific data and knowledge.

Areas for Improvement:

Although significant progress has been observed in certain areas of impartiality in the region, there are opportunities for improvement in crucial aspects:

- **Science and Evidence Criteria:** Greater emphasis is needed on decision-making based on scientific data and solid evidence, which would contribute to more effective and reliable regulations.
- **Exemption from Conflicts of Interest:** Although this area shows strengths, there is still room for improvement; it is necessary to continue strengthening existing mechanisms to ensure objectivity in regulatory decision-making, implementing more robust transparency measures and control systems that prevent any bias in regulatory processes.

The implementation of these improvements could significantly elevate the quality and reliability of regulatory systems in the region, promoting a fairer and more efficient environment for all stakeholders involved

Reference to Consider (Good Practices from Other Countries):

The World Health Organization (WHO) stands as a global reference in promoting GRP for pharmaceutical products, with particular emphasis on the principle of impartiality. Through its medicine prequalification program, WHO has established international standards to ensure the quality, safety, and efficacy of medicines. This program includes rigorous evaluation and monitoring processes based on objective and transparent scientific criteria. WHO also provides detailed guidelines on conflict of interest management and promotion of transparency in regulatory processes, which serve as a model for national regulatory agencies worldwide *(Source: World Health Organization, 2023)*

Recommendations

Based on feedback received from participants and the analysis conducted, the following recommendations are proposed to improve regulatory impartiality in the region:

- Strengthen the institutional independence of regulatory agencies through the implementation of robust legal frameworks that ensure their operational and financial autonomy. This could include creating independent funding mechanisms and transparent appointment processes for senior positions.
- Improve the application of scientific and evidence-based criteria in regulatory decision-making. This can be achieved through continuous training of regulatory personnel, collaboration with academic and research institutions, and implementation of peer review systems for critical decisions.
- Reinforce conflict of interest prevention and management mechanisms, including the implementation of stricter interest declaration policies, periodic rotation of personnel in key positions, and the creation of independent ethics committees to oversee these processes.
- Foster transparency in regulatory processes through regular publication of detailed reports on decisions made, criteria used, and results obtained. This could include creating easily accessible online platforms for the public.
- Promote regional harmonization of regulatory practices related to impartiality, facilitating the exchange of best practices among countries and the adoption of common standards.

The implementation of these recommendations would significantly contribute to improving impartiality in regulatory systems, strengthening public trust in regulatory institutions, and promoting a fairer and more efficient environment for all stakeholders in the pharmaceutical sector.

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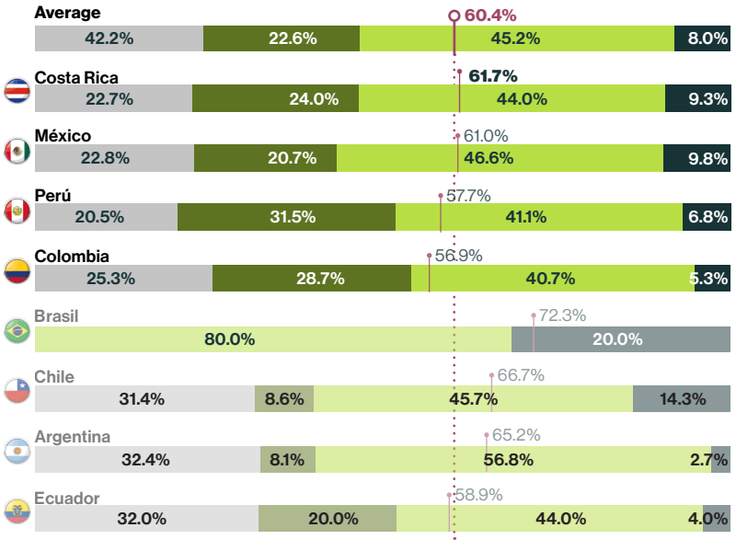
Proportionality

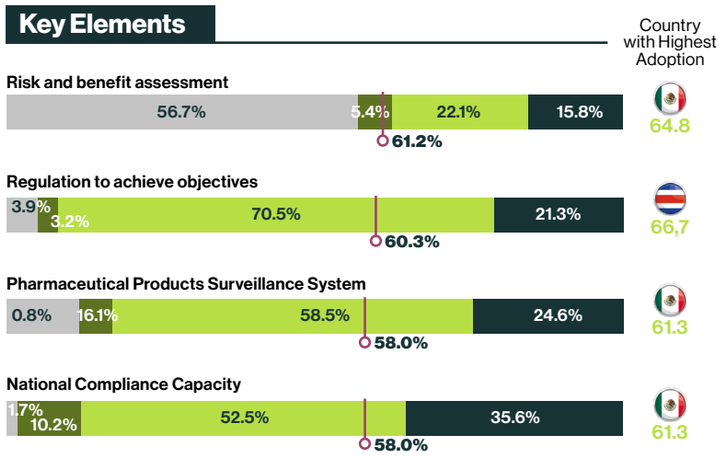
Regulation and regulatory decisions must be proportional to the risk and the regulator's capacity to implement and enforce them *(WHO.2022)*.

Regional Overview



Graph 9.

Key Elements



Graph 10.

No opinion *Basic* *Intermediate* *Advanced* *Average*

The LATAM score for the principle of proportionality *(Graph 9)* stands at a **medium level of 60.4**. This result reflects moderate progress in adopting regulations and regulatory decisions proportional to risk and regulator capacity in the region. The graph shows variability among analyzed countries, with scores ranging between **56.9 and 61.7** for Colombia, Costa Rica, Mexico, and Peru. This data suggests that, while there is a common foundation, there are differences in the implementation of this principle among the mentioned countries.

The key elements with the highest adoption are "Risk and Benefit Assessment and Regulation to Achieve Objectives," showing a medium level of implementation *(Graph 6)*. The key elements showing the greatest lag are "Pharmaceutical Products Surveillance System" and "National Compliance Capacity." In summary, Latin America shows progress in pharmaceutical regulation but faces significant challenges in regulatory impact assessments and compliance capabilities

Strengths:

The principle of proportionality shows significant strengths in two Latin American countries:

Costa Rica: Stands out in "Regulation to Achieve Objectives," suggesting a clear and effective approach in implementing outcome-oriented regulations.

México leads in several key elements:

- Excels in "Risk and Benefit Assessment", indicating a commitment to rigorous evaluation of regulatory implications before implementation.
- Leads in "National Compliance Capacity", reflecting a robust infrastructure to ensure adherence to established regulations.
- Stands out in "Pharmaceutical Products Surveillance System", suggesting an effective system for monitoring and controlling the quality and safety of medicines in the market.

Areas for Improvement:

The analysis reveals areas with the greatest lags in applying the principle of proportionality in the region, presenting significant opportunities for improvement, such as:

- **National Compliance Capacity:** Strengthen institutional capabilities to ensure effective regulatory compliance.
- **Pharmaceutical Products Surveillance System:** Strengthen post-marketing monitoring mechanisms to ensure medicine safety and efficacy throughout their lifecycle.

It is crucial to prioritize these areas of improvement to strengthen regulatory systems and ensure a balance between innovation, safety, and access to medicines.

References to Consider (Good Practices from Other Countries):

Health Canada, Canada's health product regulatory agency, stands out for its innovative approach in applying the principle of proportionality. The agency has implemented a flexible regulatory framework known as "Regulatory Innovation Agenda," which seeks to balance public health protection with innovation promotion. This framework includes tools such as the "Regulatory Sandbox" that allows testing new regulatory approaches in a controlled environment, and the "Agile Licensing Framework" for medicines, which adapts regulatory requirements according to the product's risk-benefit profile. Health Canada has also been a pioneer in implementing a "Rolling Review" system for priority products, allowing faster and proportional evaluation of medicines addressing unmet medical needs. *(Source: Health Canada, 2024)*

Recommendations

Based on feedback received from participants and the analysis conducted, the following recommendations are proposed to improve regulatory proportionality in the region:

- Regulatory control should be adequate to achieve the objectives without being excessive.
- Regulatory measures should be proportionate to the risk of the product, activity or service.
- Regulations should not exceed national capacity to implement and enforce them.
- Evaluation of medical products should be based on a risk-benefit assessment and continuous monitoring of the risk-benefit profile in a robust surveillance system.

The implementation of these recommendations will contribute to strengthening regulatory systems in Latin America, ensuring an appropriate balance between public health protection, innovation promotion, and access to safe and effective medicines.

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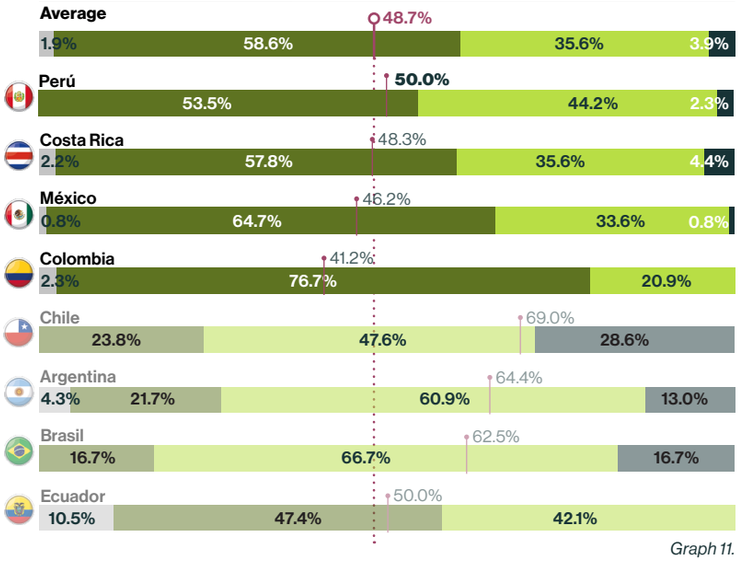
Flexibility

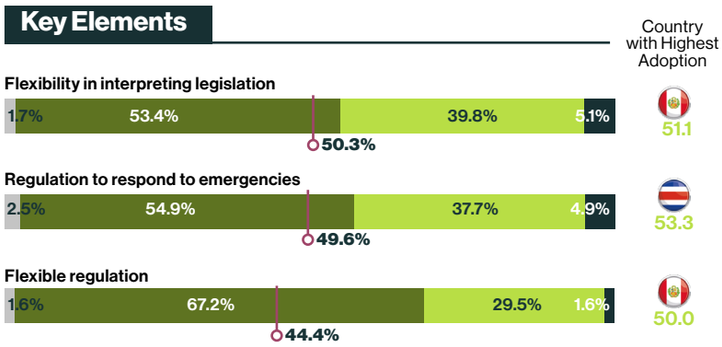
Regulatory oversight should not be prescriptive but flexible to respond to a changing environment and unforeseen circumstances. Timely responsiveness to specific needs and especially public health emergencies should be integrated into the regulatory system *(WHO.2022).*

Regional Overview



Graph 11.

Key Elements



Graph 12.

No opinion *Basic* *Intermediate* *Advanced* *Average*

The average for the principle of flexibility *(Graph 11)* stands at a **medium level of 48.7**. This result reflects moderate progress in the adoption of flexible and adaptable regulations in the region's pharmaceutical sector. Graph 11 shows variability among analyzed countries, with scores ranging between **41.2 and 50.0** for Colombia, Costa Rica, Mexico, and Peru. Colombia shows the **lowest score at 41.2**, while Peru shows the **highest at 50.0** among these countries.

The key elements with the highest adoption are "Regulation to respond to emergencies" and "Flexibility in Interpreting Legislation". The key element showing the greatest lag is "Flexible Regulation". In summary, while there is progress in emergency response and interpretative flexibility, the region still needs significant improvement in implementing more flexible regulations and advanced legislative interpretations.

Strengths:

The principle of flexibility shows significant strengths in two Latin American countries, which are presented below:

- **Perú:** Stands out in "Flexibility in Interpreting Legislation", indicating significant capacity to adapt the interpretation of regulations as needed. Additionally, it excels in "Flexible Regulation", suggesting a solid foundation for implementing adaptable regulations.
- **Costa Rica:** Leads in "Regulation to respond to emergencies", implying notable capacity to quickly adjust regulations in critical situations

Areas for Improvement:

The main areas for improvement in the principle of flexibility focus on the following areas:

- **Flexible Regulation:** There is significant lag in implementing adaptable regulations, especially at advanced levels. Greater effort is required to develop regulatory frameworks that can quickly adjust to technological changes and market needs.
- **Regulation to respond to emergencies:** While this key element shows better performance, there is still room for improvement in implementing advanced mechanisms that allow for more agile and effective regulatory response in health crisis situations.

Addressing these opportunity areas will allow the region to develop a more adaptable and efficient regulatory framework, improving the pharmaceutical sector's response capacity to emerging challenges and changing market needs.

Reference to Consider (Good Practices from Other Countries):

The UK Medicines and Healthcare products Regulatory Agency (MHRA) is a reference in regulatory flexibility for pharmaceutical products. Its "Early Access to Medicines Scheme" (EAMS) allows patients with life-threatening or seriously debilitating conditions to access medicines before formal approval. Additionally, MHRA has implemented the "Innovative Licensing and Access Pathway" (ILAP), which provides a flexible and collaborative approach to the development and approval of innovative medicines. These programs demonstrate a commitment to innovation and regulatory flexibility while maintaining high standards of safety and efficacy. *(Source: Medicines and Healthcare products Regulatory Agency [MHRA], 2024).*

Recommendations

Based on feedback received from participants and the analysis conducted, the following recommendations are proposed to improve regulatory flexibility in the region:

- Implement a more adaptable regulatory framework that allows quick response to health emergencies and technological changes, similar to EMA's "adaptive pathways" approach.
- Develop training programs for regulatory officials on flexible interpretation of legislation, maintaining balance between adaptability and regulatory compliance.
- Establish consultation and collaboration mechanisms between regulatory agencies and industry to identify areas where regulatory flexibility can improve efficiency without compromising safety.
- Promote regional harmonization of flexible regulatory practices, facilitating the exchange of experiences and best practices among Latin American countries.
- Implement continuous evaluation systems to measure the effectiveness of regulatory flexibilities and make necessary adjustments, ensuring a continuous improvement approach in pharmaceutical regulation that allows timely access and continuity in therapy supply for patients. Additionally, it is recommended to consider user surveys, analysis of frequently asked questions, and periodic reviews of current regulations.

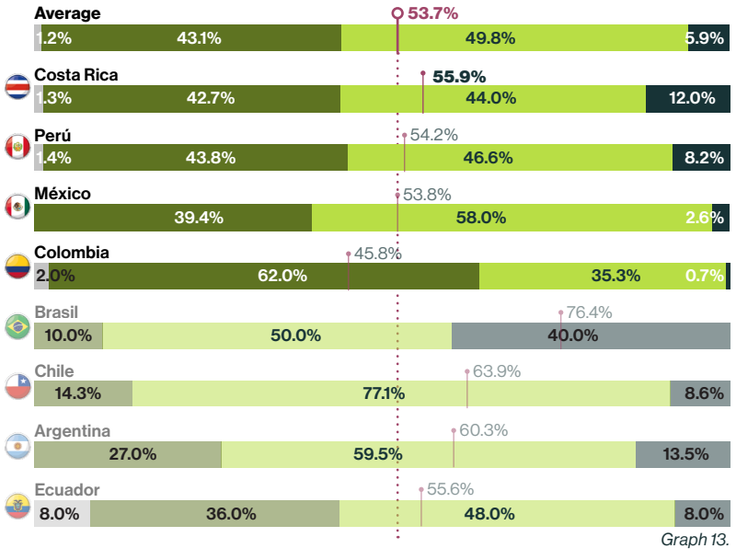
These recommendations seek to address the opportunity areas identified in the analysis, such as the need to improve regulatory flexibility in emergency situations and the ability to interpret legislation more adaptably, while maintaining quality and safety standards in the region's pharmaceutical industry.

This document does not include data from the following countries: Brazil, Argentina, Chile, and Ecuador due to low representativeness in the responses to the instrument used in the study.

Clarity

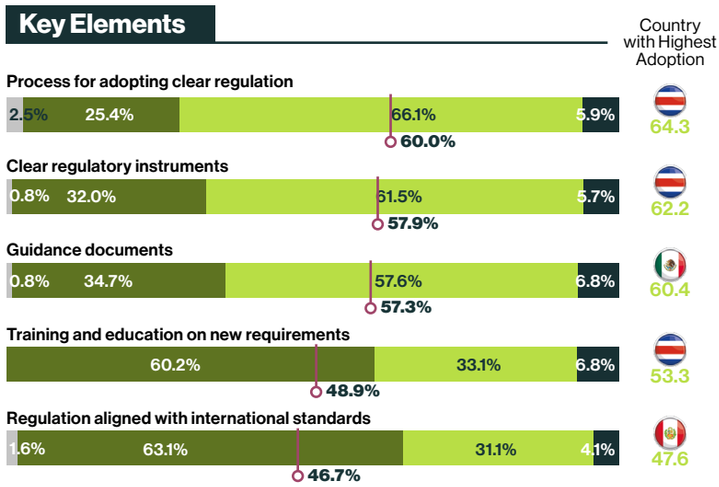
Regulatory requirements must be accessible to users and understood by them. *(WHO.2022)*.

Regional Overview



Graph 13.

Key Elements



Graph 14.

No opinion *Basic* *Intermediate* *Advanced* *Average*

The average for the clarity principle *(Graph 13)* stands at a **medium level of 53.7**. This result reflects moderate progress in the adoption of accessible and understandable regulatory requirements for users in the pharmaceutical sector. The graph shows variability among analyzed countries, with scores ranging between **45.8 and 55.9** for Colombia, Costa Rica, Mexico, and Peru. Colombia shows the **lowest score at 45.8**, while Costa Rica shows the **highest at 55.9** among these countries.

The key elements with the highest adoption in the region are "Process for adopting clear regulation" and "clear regulatory instruments" with higher medium and advanced levels. On the other hand, the key elements showing the greatest lag are "Regulation aligned with international standards" and "Training and Education on New Requirements". These aspects require attention, as they indicate the need to improve the clarity of regulatory instruments and strengthen training on new regulations in these Latin American countries. *(Graph 14)*.

Strengths:

The clarity principle shows significant strengths in several Latin American countries, which are presented below:

- **Costa Rica:** Stands out in "Process for Adopting Clear Regulation", indicating a commitment to transparency in implementing new regulations.
- **México:** Excels in "Guidance Documents", implying an effort to provide clear and accessible information about regulations.
- **Perú:** Leads in "Regulation Aligned with International Standards" at the basic level, suggesting a focus on adopting international standards.

Areas for Improvement:

The main areas for improvement in the region focus on the following key elements:

- **Regulation aligned with international standards:** it is important to continue strengthening alignment with global standards to improve regulatory harmonization and facilitate international trade of pharmaceutical products.
- **Guidance Documents:** While this category shows positive performance, it is important to strengthen the development and continuous updating of detailed technical guidelines, ensuring they are accessible, understandable, and cover all relevant aspects of the regulatory process. This will facilitate correct interpretation and application of regulations by industry.
- **Training and Education on New Requirements:** It is necessary to strengthen training and dissemination programs on new regulations, ensuring all stakeholders are well-informed and prepared to implement regulatory changes effectively.

Strengthening these areas will contribute significantly to improving regulatory clarity in the region, facilitating regulatory compliance and promoting a more efficient and transparent regulatory environment for the pharmaceutical industry.

Reference to Consider (Good Practices from Other Countries):

A global reference in regulatory good practices for clarity in pharmaceutical product regulation is the European Medicines Agency (EMA). The EMA stands out for its focus on transparency and clarity in its regulatory processes, providing detailed guidelines, question and answer documents, and interactive tools to facilitate understanding of regulatory requirements. Its web portal offers clear and accessible information on authorization procedures, pharmacovigilance, and other key regulatory aspects. Additionally, the EMA maintains constant dialogue with stakeholders to improve the clarity of its communications and regulations *(Source: European Medicines Agency [EMA], 2024).*

Recommendations

Based on feedback received from participants and the analysis conducted, the following recommendations are proposed to improve clarity in the region:

- **Strengthen alignment with international standards:** It is recommended that regulatory agencies in the region continue their efforts to harmonize their regulations with international best practices, such as those of ICH and WHO. This will improve the clarity and coherence of regulations at regional and international levels.
- **Improve clarity of regulatory instruments:** It is crucial to develop and publish guidelines, directives, and normative documents that are clear, concise, and easily understandable for all sector stakeholders. It is suggested to use simple language and provide practical examples when possible.
- **Develop and maintain updated guidance documents:** It is recommended to create and periodically update detailed guidelines that explain regulatory processes, requirements, and expectations. These guidelines should be easily accessible on agency websites and other relevant communication channels.
- **Establish clear processes for adopting new regulations:** It is important to implement transparent and well-defined procedures for introducing new regulations or modifications to existing ones. This should include public consultation periods and clear communication of regulatory process timelines and stages.
- **Promote stakeholder participation**: It is recommended to establish formal mechanisms for industry, academia, and other relevant actors' participation in regulatory development and review. This may include working groups, discussion forums, and public comment periods.
- **Implement a continuous evaluation system:** Regulatory agencies should establish mechanisms to regularly evaluate the clarity and effectiveness of their regulations and processes, that is, a regulatory agenda. This may include user surveys, analysis of frequently asked questions, and periodic reviews of existing regulations.

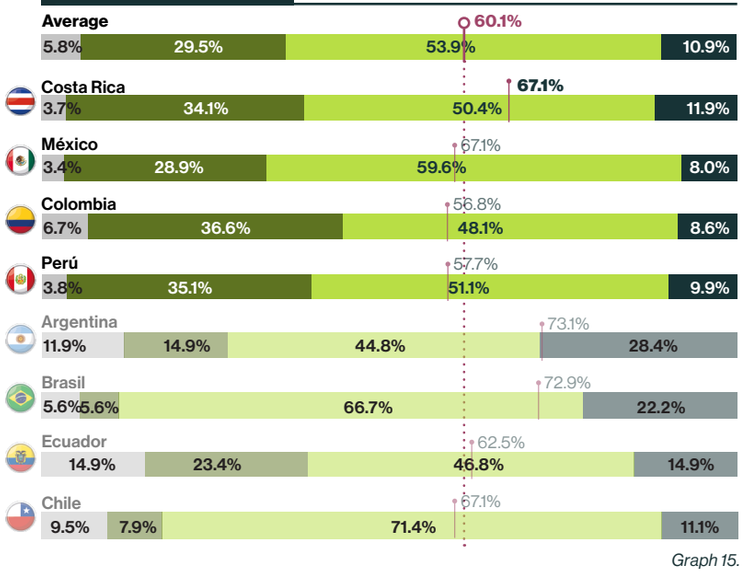
The implementation of these recommendations will contribute significantly to improving regulatory clarity in the region, facilitating regulatory compliance and promoting a more efficient and transparent regulatory environment for the pharmaceutical industry.

This document does not include data from the following countries: Brazil, Argentina, Chile, and Ecuador due to low representativeness in the responses to the instrument used in the study.

Efficiency

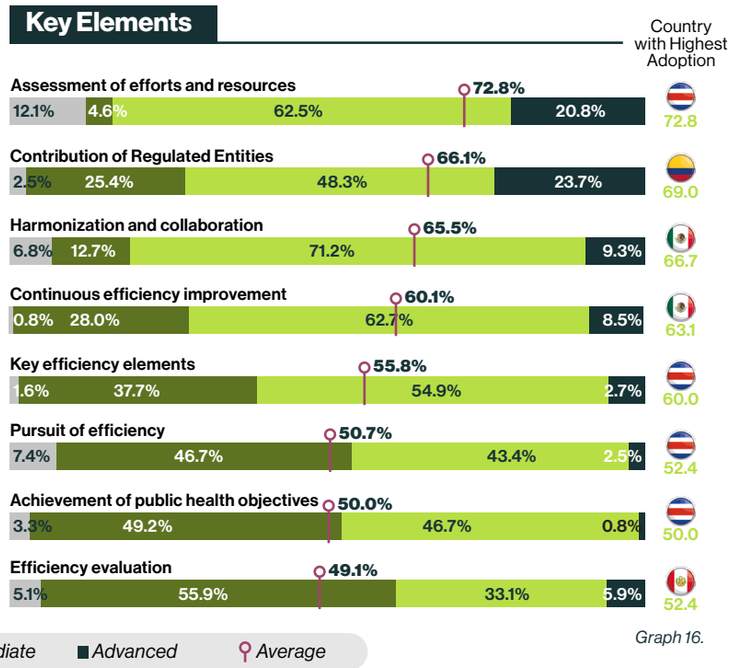
Regulatory efficiency refers to regulatory systems achieving their objectives within the required timeframe and with reasonable effort and cost. International collaboration promotes efficiency by ensuring the best use of resources *(WHO.2022)*.

Regional Overview



Graph 15.

Key Elements



Graph 16.

The average for the efficiency principle *(Graph 15)* stands at a medium level of **60.1**. This result reflects moderate progress in implementing efficient regulatory systems in the pharmaceutical region. The graph shows variability among analyzed countries, with scores ranging between **57.7 and 67.1** for Colombia, Costa Rica, Mexico, and Peru. This data suggests that, while there is progress, there is still room for improvement in terms of regulatory efficiency in these Latin American countries.

The key elements with the highest adoption are "Assessment of Efforts and Resources" and "Contribution of Regulated Entities". The key elements showing the greatest lag are "Efficiency Evaluation" and "Achievement of Public Health Objectives". These results indicate that, while there is effort in resource allocation and participation of regulated entities, there is an opportunity for improvement in the evaluation and continuous optimization of efficiency in pharmaceutical product regulatory systems in the region. *(Graph 16)*

Strengths:

The efficiency principle shows significant strengths in several Latin American countries, which are presented below:

- **Costa Rica:** stands out in "Assessment of Efforts and Resources," indicating efficient management of available resources. It also excels in "Achievement of Public Health Objectives," suggesting an effective approach to achieving health goals.
- **México:** leads in "International Harmonization and Collaboration," implying a strong commitment to global regulatory cooperation. Additionally, it excels in "Continuous Efficiency Improvement," suggesting a proactive approach to constant optimization of its regulatory processes.
- **Colombia:** excels in "Contribution of Regulated Entities," indicating excellent collaboration and participation from the regulated sector in regulatory processes.
- **Perú:** leads in "Efficiency Evaluation" with a more advanced approach to measuring and analyzing the effectiveness of its regulatory processes.

Areas for Improvement:

The opportunities for improvement in the efficiency principle primarily focus on key elements showing significant lag in the region:

- **Efficiency Evaluation and Continuous Improvement:** It is necessary to improve systematic evaluation mechanisms and optimization of regulatory processes, implementing performance indicators and continuous improvement methodologies.
- **Achievement of Public Health Objectives:** Mechanisms need to be implemented to measure and evaluate the impact of regulations on public health outcomes, ensuring policies are aligned with national health objectives.
- **Pursuit of Efficiency:** There is a lag in implementing strategies to optimize regulatory processes, reducing response times and administrative costs without compromising medical product quality and safety.
- **International Harmonization and Participation of Regulated Entities:** It is necessary to align practices with global standards and promote greater collaboration with regulatory agencies and sector entities.

Reference to Consider (Good Practices from Other Countries):

ANVISA has implemented and perfected GRP from 2008 to 2021, aiming to improve the quality and effectiveness of regulatory processes. This has resulted in significant advances in terms of safety, quality, and effectiveness of regulated products. Among the most notable achievements are the creation of the Good Regulatory Practices Guide and the implementation of Regulatory Impact Analysis (RIA) in all normative processes. Anvisa is also a reference with its strong international harmonization, including its participation in forums such as ICH, IMDRF & PIC/S, and in the adoption of risk-based assessments and regulatory reliance. ***(Source: Anvisa, 2024).***

Recommendations

Based on feedback received from participants and the analysis conducted, the following recommendations are proposed to improve efficiency in the region:

- **Adopt Regulatory Reliance Mechanisms for different functions:** to improve efficiency and accelerate approval processes. This strategy will optimize resources and facilitate faster access to pharmaceutical innovations in the region.
- **Strengthen international harmonization:** Intensify collaboration with global regulatory agencies to adopt best practices and international standards, facilitating regulatory convergence.
- **Optimize resource allocation:** Develop mechanisms to evaluate and improve the distribution of human and financial resources, prioritizing critical areas for regulatory efficiency.
- **Foster participation of regulated entities:** Establish more effective communication channels with industry to receive feedback and continuously improve regulatory processes.
- **Implement performance indicators:** Develop and use clear metrics to measure the efficiency of regulatory processes, allowing objective evaluation and identification of areas for improvement.
- **Promote digitalization and AI use:** Accelerate the adoption of digital technologies to streamline processes, improve data management, and facilitate communication among all stakeholders.

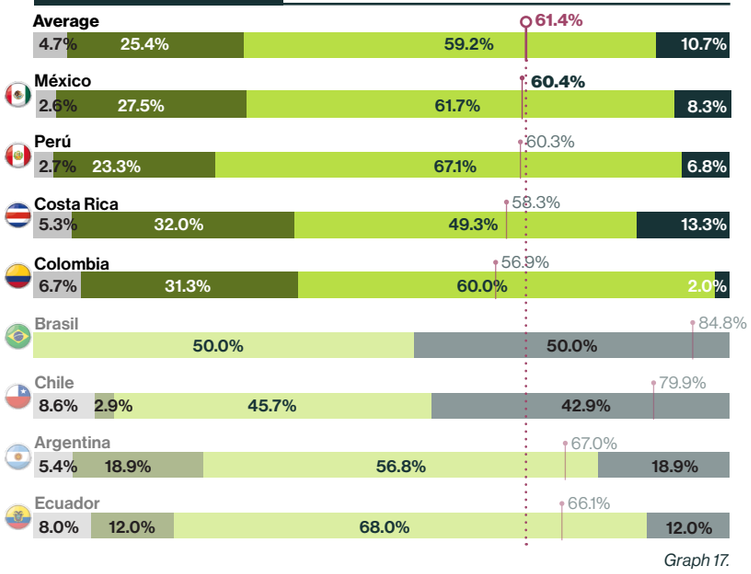
These recommendations seek to address the opportunity areas identified in the analysis, such as the need to improve evaluation and continuous optimization of efficiency, as well as strengthen international harmonization and participation of regulated entities. The implementation of these measures could significantly contribute to improving the overall efficiency of regulatory systems in the region, benefiting both industry and patients.

This document does not include data from the following countries: Brazil, Argentina, Chile, and Ecuador due to low representativeness in the responses to the instrument used in the study.

Transparency

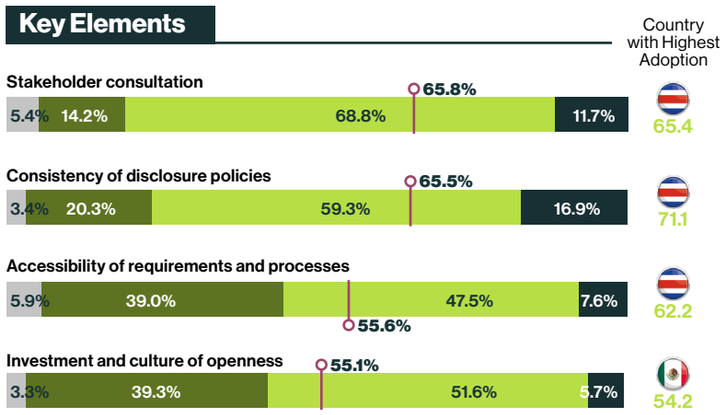
Regulatory systems must be transparent, requirements and decisions must be disclosed, and input must be sought on regulatory proposals *(WHO.2022)*.

Regional Overview



Graph 17.

Key Elements



Graph 18.

No opinion *Basic* *Intermediate* *Advanced* *Average*

The average for the transparency principle *(Graph 17)* stands at a **medium level of 61.4**. This result reflects moderate progress in implementing transparent practices in pharmaceutical product regulatory systems in the region. The graph shows variability among analyzed countries, with scores ranging between **56.9 and 60.4** for Colombia, Costa Rica, Mexico, and Peru. This variation suggests that, while there is general progress, there are differences in the degree of adoption of transparency measures among these countries.

The key elements with the highest adoption in the region are "Stakeholder Consultation" and "Consistency of Disclosure Policies," with higher medium and advanced levels *(Graph 18)*. On the other hand, the areas showing the greatest lag are "Investment and Culture of Openness" and "Accessibility of Requirements and Processes." These results indicate that, while significant progress has been made in stakeholder participation and consistency in policy disclosure, there are still opportunities for improvement in promoting a culture of openness and facilitating access to regulatory information.

Strengths:

The transparency principle shows significant strengths in two Latin American countries, which are presented below:

- **Costa Rica:** Leader in "Stakeholder Consultation," suggesting an inclusive approach to regulatory processes. It also stands out in "Consistency of Disclosure Policies," indicating a commitment to consistency in regulatory information communication. Additionally, it shows strength in "Accessibility of Requirements and Processes," pointing to a focus on facilitating understanding and compliance with regulations.
- **México:** Excels in "Investment and Culture of Openness," implying an effort to promote transparency in the regulatory system.

Areas for Improvement:

The analysis reveals the areas with the greatest gaps in applying the transparency principle in the region, presenting significant opportunities for improvement, such as:

- **Investment and Culture of Openness:** there are evident gaps in strengthening commitment to transparency in regulatory systems.
- **Accessibility of requirements and processes:** Work is needed on access to information about regulatory requirements and processes.
- **Consistency of Disclosure Policies:** It is necessary to implement disclosure policies more uniformly across the region.

By addressing these areas for improvement, the analyzed countries will be able to significantly strengthen transparency in their regulatory systems, which in turn will contribute to greater efficiency, public trust, and alignment with international best practices in pharmaceutical product regulation.

Reference to Consider (Good Practices from Other Countries):

The European Medicines Agency (EMA) stands out for its focus on transparency in regulatory processes. Its web portal provides clear and accessible information about authorization procedures, pharmacovigilance, and other key regulatory aspects. Additionally, the EMA maintains constant dialogue with stakeholders to improve the clarity of its regulations (Source: European Medicines Agency [EMA], 2024).

Recommendations

Based on feedback received from participants and the analysis conducted, the following recommendations are proposed to improve transparency in the region:

- Strengthen investment in information systems and technology to improve accessibility and dissemination of regulatory information. This includes developing intuitive and user-friendly online platforms that centralize all relevant information.
- Implement training and awareness programs for public officials on the importance of transparency and best practices for its application in the regulatory field.
- Establish formal and structured mechanisms for stakeholder consultation, ensuring their inputs are considered and reflected in final regulatory decisions.
- Develop and publish clear guidelines on regulatory processes, requirements, and evaluation criteria, using language accessible to all stakeholders.
- Implement a continuous monitoring and evaluation system for transparency practices, with clear indicators and periodic progress reports.
- Foster regional collaboration to share best practices and develop common transparency standards in pharmaceutical product regulation.
- Establish clear information disclosure policies, including proactive publication of evaluation reports, clinical data, and regulatory decisions, following the example of agencies like the EMA.

The implementation of these recommendations will significantly contribute to improving transparency in regulatory systems, strengthening public trust, facilitating informed decision-making, and promoting more efficient and effective regulation of pharmaceutical products in the region.

This document does not include data from the following countries: Brazil, Argentina, Chile, and Ecuador due to low representativeness in the responses to the instrument used in the study.

6.3

Enablers

Enablers play a crucial role in the effective implementation of GRP in pharmaceutical product regulatory systems. These elements are fundamental for creating an enabling environment that allows for the adoption and maintenance of sound regulatory principles. In the context of this study, enablers refer to those factors that support and enhance the capacity of regulatory agencies to carry out their functions efficiently, transparently, and based on evidence.

The relevance of enablers in this study lies in their capacity to:

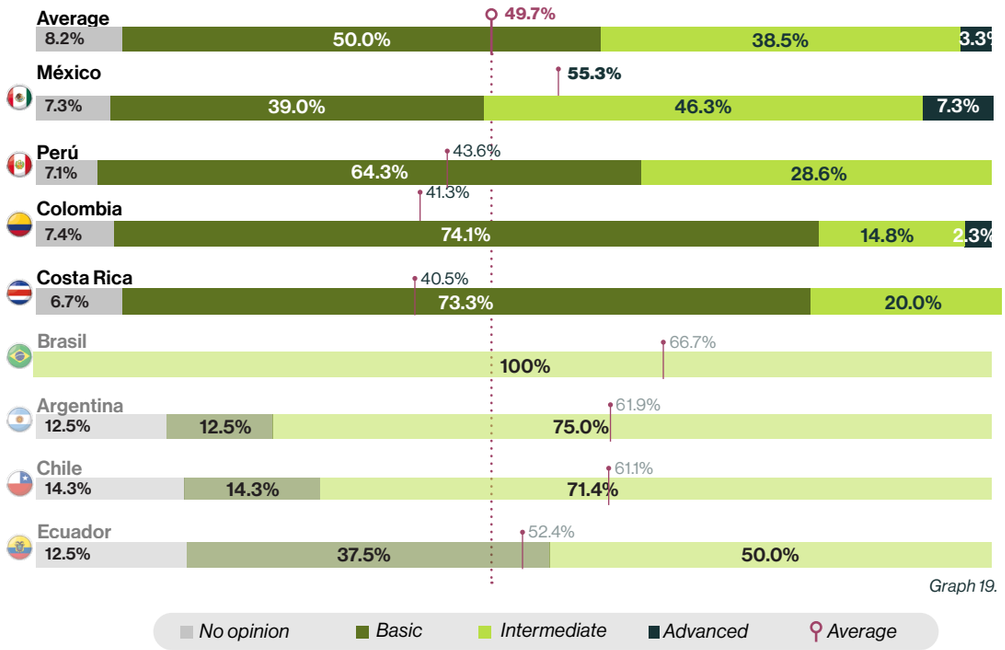
- Strengthen the institutional infrastructure necessary to implement GRP.
- Promote sustainability and continuous improvement of regulatory systems.
- Increase public trust in regulatory processes.
- Facilitate international harmonization and collaboration in regulatory matters.

By evaluating these enablers, we can identify areas of strength and opportunities for improvement in the regulatory systems of the analyzed countries. This provides a solid foundation for formulating specific and strategic recommendations that can drive the adoption of GRP in the region, thus improving the effectiveness and efficiency of pharmaceutical product regulation

Political and Whole-of-Government Support

Sustained support from the highest political and governmental levels, including policy-makers, is paramount for the proper application of good regulatory practices concepts and principles. These good practices must be an integral part of all government policies on regulatory systems and have strong political support. *(WHO, 2022)*

Regional Overview



Graph 19.

The graph shows that Mexico leads the region in adoption of the "Political and Whole-of-Government Support" enabler, with the best average performance **(55.3%)**, standing out for significant progress compared to other countries. Following are Peru and Colombia, which show moderate performance with averages of **43.6% and 41.3%**, respectively. Finally, Costa Rica ranks with the lowest adoption level among the countries considered, with an average of **40.5%**, reflecting a lag compared to the rest. This demonstrates significant differences in adoption within the region, with Mexico showing leadership.

Reference to Consider (Good Practices from Other Countries):

The FDA is a global reference in political and governmental support for pharmaceutical regulation. It has implemented a robust GRP system with a comprehensive approach, from research to post-marketing pharmacovigilance. Its rigorous and transparent standards serve as a global model (Source: U.S. Food and Drug Administration [FDA], 2023).

Recommendations

Establish inter-institutional coordination mechanisms for coherent implementation

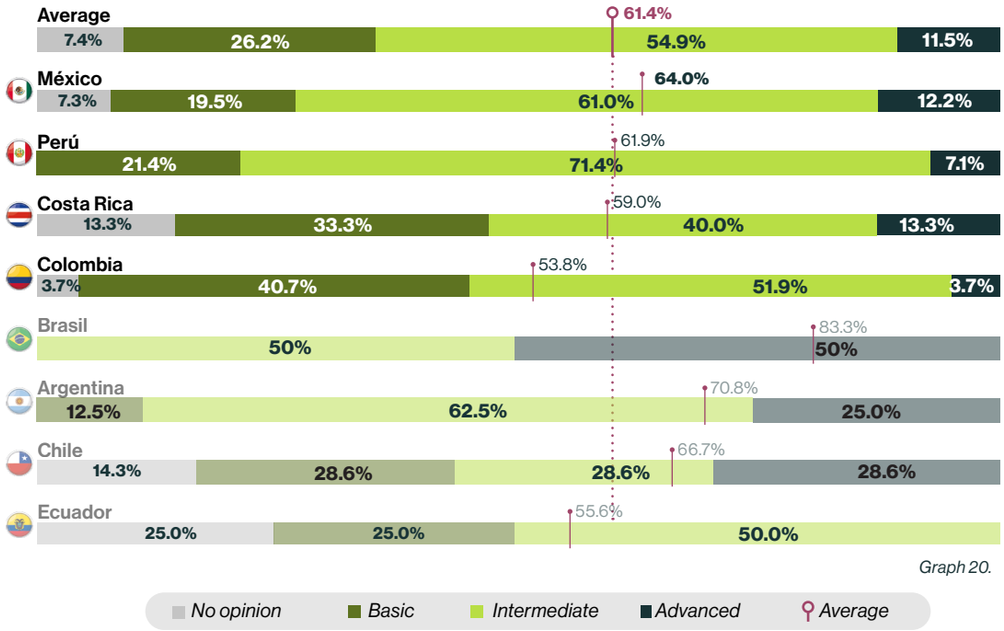
- Velar por una asignación adecuada de recursos para el Sistema Regulatorio.
- Desarrollar estrategias de comunicación para sensibilizar a líderes sobre la importancia de las BPR.
- Fortalecer el marco legal y normativo, integrando las BPR en políticas nacionales.
- Implementar programas de capacitación continua sobre BPR para funcionarios públicos.
- Promover la participación en foros internacionales para compartir experiencias en BPR.

This document does not include data from the following countries: Brazil, Argentina, Chile, and Ecuador due to low representativeness in the responses to the instrument used in the study.

Effective Organization and Good Governance Supported Through Leadership

The structure and lines of authority between and within all institutions of the regulatory system must be well-defined. The integrity of the overall regulatory system is fundamental to the efficient performance of each of its constituent institutions. If more than one institution participates in the regulatory system, legislation or institutional regulation must provide for clear coordination without overlap of regulatory activities. Leadership is essential to establish and realize the organization's vision, mission, policies, and strategies, which in turn contribute significantly to its efficiency *(WHO, 2022)*

Regional Overview



Graph 20.

The graph shows that Mexico leads in the adoption of the "Effective Organization and Good Governance Supported Through Leadership" enabler with the best average performance **(64.0%)**, standing out as the most advanced country compared to the rest of the region. Peru follows with an average of **61.9%**, also showing outstanding performance. Costa Rica ranks at an intermediate level with an average of **59.0%**, while Colombia shows a lower level of adoption with an average of **53.8%**. This highlights the differences in adoption within the region, with Mexico and Peru showing leadership, while Colombia and Costa Rica show more limited progress.

Reference to Consider (Good Practices from Other Countries):

The European Medicines Agency (EMA) is a benchmark in pharmaceutical organization and governance. Its system includes a clear structure, transparent processes, and collaboration with national authorities. Its model of scientific committees and working groups ensures rigorous and efficient evaluations. The EMA also implements innovative strategies to adapt to scientific and technological advances (European Medicines Agency [EMA], 2023).

Recommendations

Key recommendations to improve organization and governance in the analyzed countries:

- Strengthen organizational structures and clearly define roles.
- Implement leadership development programs.
- Establish coordination mechanisms between entities.
- Develop governance performance indicators.
- Foster a culture of continuous improvement and innovation.

These measures seek to promote more effective governance and stronger leadership in the region's regulatory systems.

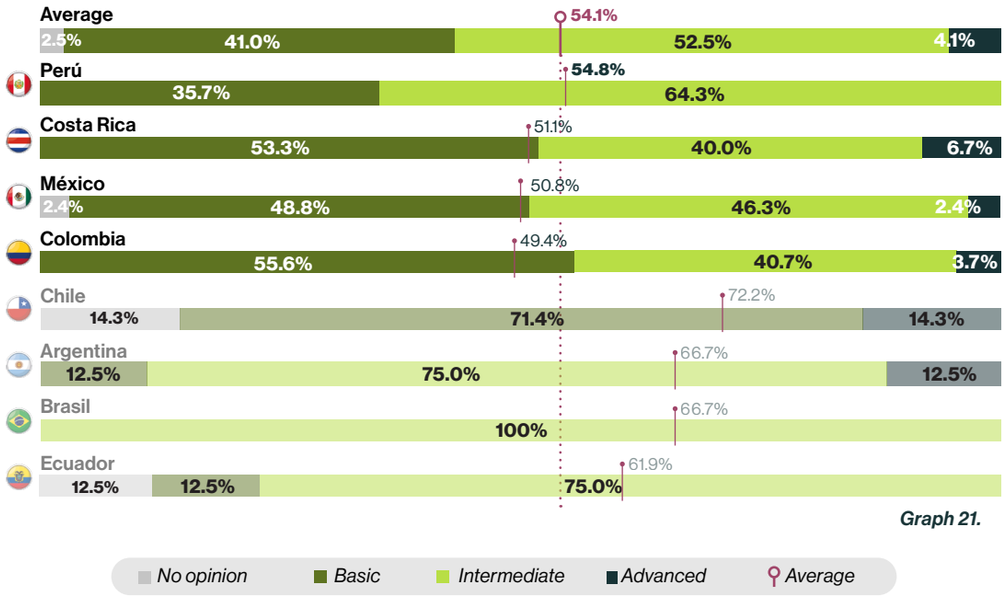
This document does not include data from the following countries: Brazil, Argentina, Chile, and Ecuador due to low representativeness in the responses to the instrument used in the study.

Inter-institutional and Intra-institutional Communication, Collaboration, and Coordination

Effective communication is fundamental for information exchange within and outside regulatory institutions. Regular communication, both internal and external, increases transparency and accountability, preventing misunderstandings and the dissemination of misleading information. Additionally, it facilitates collaboration and coordination with stakeholders, improving resource efficiency and regulatory outcomes.

Regulatory authorities must have adequate personnel, infrastructure, and technical tools for their tasks. Communication technologies can facilitate coordination and rapid information exchange, reducing duplications and gaps in the system *(WHO, 2022).*

Regional Overview



Graph 21.

The graph shows that Peru leads the region in adoption of the "Inter-institutional and Intra-institutional Communication, Collaboration, and Coordination" enabler, with the best average performance **(54.8%)**, standing out for significant progress compared to other countries, followed by Costa Rica and Mexico, which show moderate performance with averages of **51.1% and 50.8%**, respectively. Finally, Colombia ranks with the lowest adoption level among the countries considered, with an average of **49.4%**, reflecting a lag compared to the rest.

Reference to Consider (Good Practices from Other Countries):

WHO is a global reference in international pharmaceutical communication and collaboration. Its medicine prequalification program and the "WHO Collaborative Registration Procedure" platform facilitate cooperation between regulatory agencies and access to essential medicines. WHO also coordinates efforts against counterfeit medicines and publishes guidelines for global regulatory harmonization. *(Source: WHO, 2023)*

Recommendations

Key recommendations to improve communication, collaboration, and coordination in the analyzed countries:

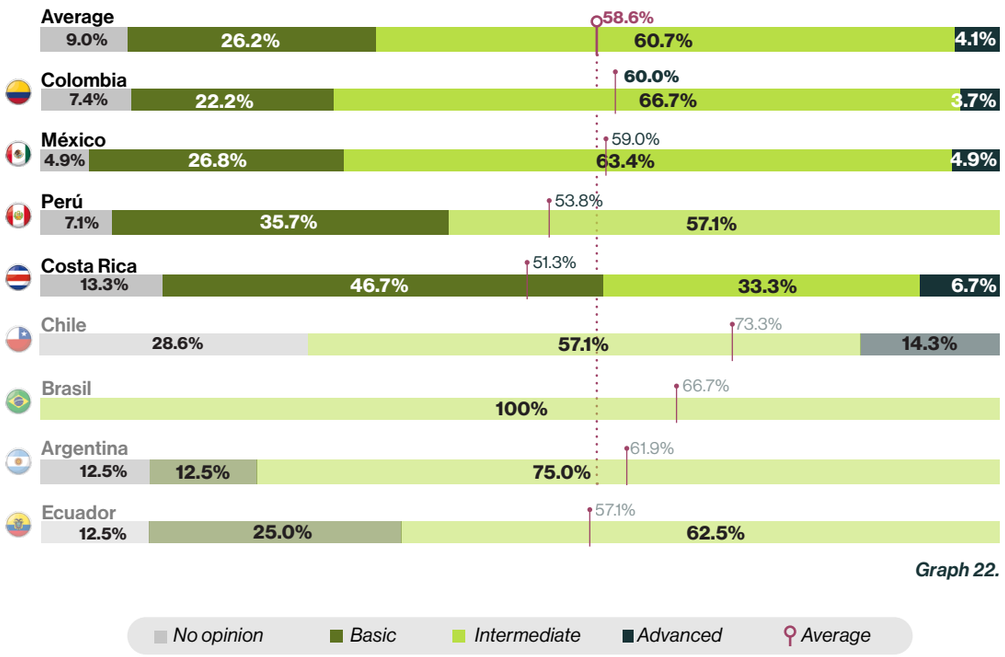
- Implement integrated digital platforms for information exchange.
- Establish exchange programs between regulatory agencies.
- Develop standardized communication protocols.
- Create permanent inter-institutional working groups.
- Promote participation in international regulatory forums.

This document does not include data from the following countries: Brazil, Argentina, Chile, and Ecuador due to low representativeness in the responses to the instrument used in the study.

Robust Quality Management System

A quality management system, which includes the application of quality risk management principles, makes regulatory authority decisions more credible and their operations more stable and consistent. A quality management system contributes to systematic planning, quality control and improvement across all regulatory function processes and ensures a comprehensive approach. *(WHO, 2022)*

Regional Overview



Graph 22.

The graph shows that Colombia leads with the best average performance **(60.0%)**, followed by Mexico with an average of **59.0%**, standing out as the countries with the highest adoption level. Peru ranks third with an average of **53.8%**, reflecting intermediate performance. Finally, Costa Rica has the lowest adoption level among the countries considered, with an average of **51.3%**. This demonstrates that Mexico and Colombia are at the forefront, while Peru and Costa Rica show more limited progress in comparison.

RefReference to Consider (Good Practices from Other Countries):

The FDA is globally recognized for its robust quality management system in pharmaceutical regulation. Its Quality Management System (QMS), based on the Total Quality approach, integrates risk management and continuous improvement across all its regulatory processes. The FDA also leads initiatives to harmonize international quality standards *(U.S. Food and Drug Administration [FDA], 2022)*

Recommendations

Key recommendations to strengthen the quality management system in the analyzed countries:

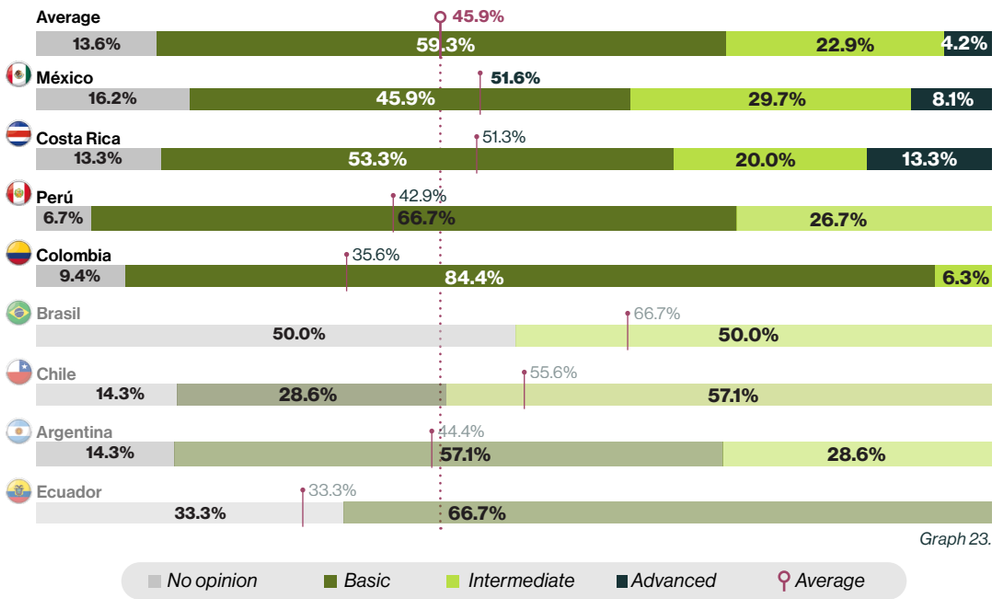
- Implement comprehensive quality management training
- Establish exchange programs between regulatory agencies.
- Foster regional collaboration and integrate advanced technologies
- Establish a risk management framework and promote quality culture.

This document does not include data from the following countries: Brazil, Argentina, Chile, and Ecuador due to low representativeness in the responses to the instrument used in the study.

Sufficient and Sustainable Financial Resources

Investment in a regulatory system is fundamental for the proper functioning of a healthcare system. Having sufficient financial resources to effectively fulfill its regulatory mandate and continuously improve the performance of regulatory activities is essential for the independence, impartiality, coherence, and efficiency of a regulatory system. The financial resources of all institutions in the regulatory system must be sustainable, apart from contributions from donors or philanthropic entities *(WHO, 2022)*

Regional Overview



Graph 23.

Mexico leads in the adoption of the "Sufficient and Sustainable Financial Resources" enabler with the best average performance **(51.6%).** Costa Rica ranks second with an average of **51.3%,** reflecting solid performance. Peru ranks third with an average of **42.9%,** while Colombia shows the lowest adoption level among the highlighted countries, with an average of 35.6%. This demonstrates a notable advantage for Mexico and Costa Rica in the region.

Reference to Consider (Good Practices from Other Countries):

The European Observatory on Health Systems and Policies provides a comparative analysis of the financing of medicine regulatory agencies in Europe. Its focus on financial sustainability, regulatory independence, and operational efficiency provides insights for better practices in financial resource management. Its reports examine funding models in different European countries, highlighting innovations and solutions to common challenges, informing policies and practices in the region and beyond. (Source: Panteli et al., 2022).

Recommendations

Key recommendations to improve financial resources in the analyzed countries:

- Develop legal frameworks for stable budgets
- Implement mixed funding models
- Establish long-term financial planning
- Foster regional collaboration to optimize costs
- Implement transparent financial management systems

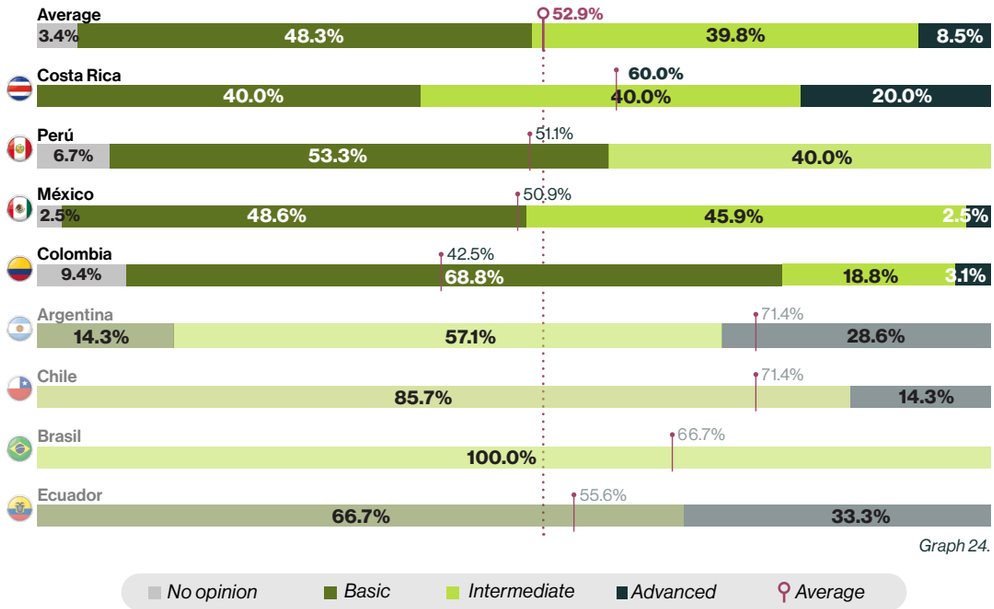
These measures seek to strengthen the financial foundation of regulatory agencies in the analyzed countries.

This document does not include data from the following countries: Brazil, Argentina, Chile, and Ecuador due to low representativeness in the responses to the instrument used in the study.

Competent Human Resources

A range of technical and scientific knowledge and skills of regulatory personnel contribute to the development, implementation, and maintenance of an effective regulatory system for pharmaceutical products. Personnel and professional development policies (for example, training programs, competitive compensation schemes) are fundamental for regulatory authorities to attract and retain competent staff in service. *(WHO, 2022)*

Regional Overview



Graph 24.

Costa Rica leads with the best average performance **(60.0%)** in the adoption of the "Competent Human Resources" enabler, standing out as the country with the highest adoption level among those considered. Peru follows with an average of **51.1%**, showing considerable progress. Mexico holds the third position with an average of **50.9%**, while Colombia shows the lowest adoption level among the analyzed countries, with an average of **42.5%**. This demonstrates that Costa Rica has a notable advantage, while Peru and Mexico show intermediate performance and Colombia lags behind in comparison.

Reference to Consider (Good Practices from Other Countries):

WHO is a global reference in human resource development for pharmaceutical regulation. Its GLO/VQ program offers training in vaccine regulation, while its "Regulatory Systems Strengthening" initiative strengthens regulatory competencies. WHO has developed a competency framework for regulators, serving as a reference for national agencies in human resource planning. (World Health Organization, 2023)

Recommendations

Key recommendations to strengthen human resources in the analyzed countries:

- Develop continuous training programs translated into measurable benefits for the regulatory system.
- Implement talent attraction and retention strategies.
- Improve compensation and benefits schemes.
- Foster international collaboration.
- Formalize agreements with academic institutions to incorporate Regulatory Affairs and related areas in the training of future professionals.

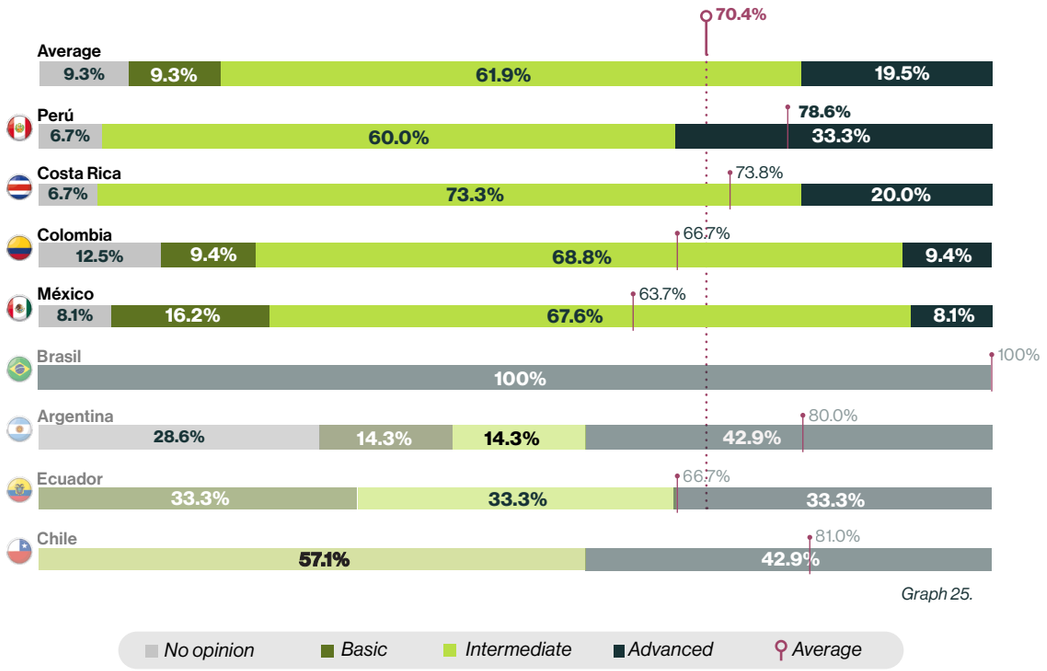
These measures seek to improve regulatory personnel capabilities in the analyzed countries.

This document does not include data from the following countries: Brazil, Argentina, Chile, and Ecuador due to low representativeness in the responses to the instrument used in the study.

Ethics and Institutional Values

Regulatory personnel must comply with the institution's ethical principles and values and demonstrate professionalism. All regulatory personnel must know and receive training on the regulatory authority's ethical principles and values (for example, a code of conduct). A system must be established, either within or outside the regulatory system, to manage deviations from ethics and institutional values *(WHO, 2022).*

Regional Overview



Graph 25.

The graph shows that Peru leads the adoption of the "Ethics and Institutional Values" enabler with the best average performance **(78.6%)**, followed by Costa Rica with an average of **73.8%**, both standing out significantly in the region. Colombia holds the third position with an average of **66.7%**, showing solid performance. Mexico, with an average of **63.7%**, closes the analysis as the country with the lowest adoption among those analyzed. This demonstrates that Peru and Costa Rica are at the forefront, while Colombia and Mexico maintain an intermediate level of adoption in comparison.

Reference to Consider (Good Practices from Other Countries):

WHO is a global reference in ethics and values for pharmaceutical regulation. Its "Ethics and Compliance Program" covers conflict prevention and transparency. Its "Code of Ethics and Professional Conduct" is widely adopted. WHO leads initiatives to harmonize ethical standards, promoting integrity in global health systems (World Health Organization, 2022).

Recommendations

Key recommendations to strengthen ethics and institutional values at the level of the analyzed countries:

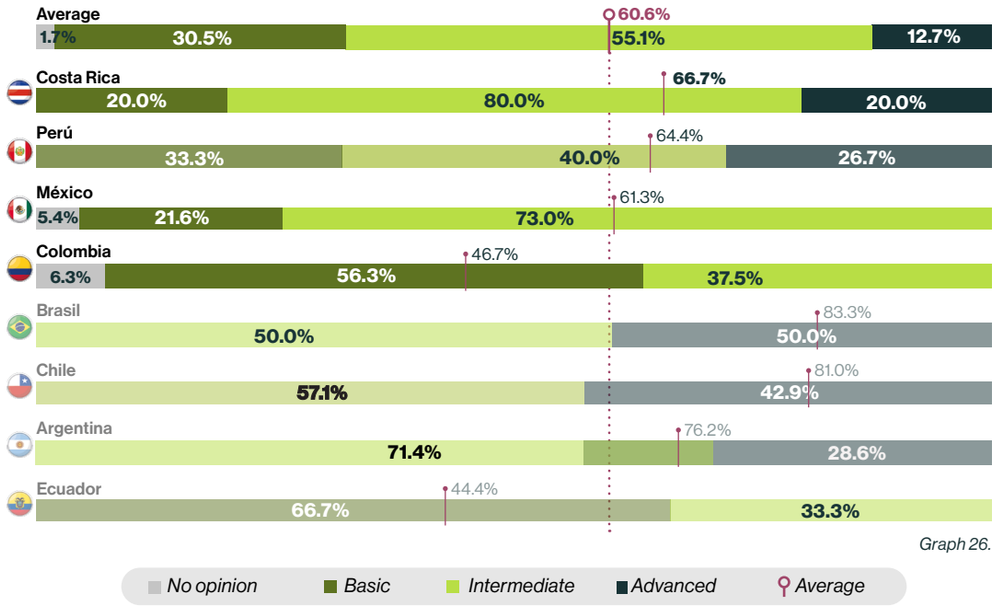
- Implement continuous ethics and values training: Establish periodic training programs that strengthen the understanding and application of ethical principles and organizational values at all levels. These programs should be regularly updated to address new ethical challenges and ensure staff alignment with best practices in professional ethics.
- Strengthen codes of conduct applicable to all levels: Review and update codes of conduct to be clear, accessible, and relevant for all collaborators, regardless of their position in the organization.
- Establish mechanisms to manage ethical conflicts: Create formal protocols that allow for the identification, reporting, and management of ethical conflicts fairly and effectively. This includes designating ethics committees or contact points in the organization that can provide advice and resolve ethical dilemmas impartially.
- Foster transparency with secure reporting systems: Implement reporting systems that protect the confidentiality and security of those who report inappropriate conduct or ethical breaches. These systems must be accessible and promote a culture of trust where collaborators feel safe reporting any ethical concerns without fear of retaliation.
- Promote regional collaboration in ethical practices: Foster collaboration and exchange of best ethical practices between organizations and authorities in the region. This may include creating forums or working groups that facilitate discussion on ethics in the regulatory field and the adoption of common standards that strengthen ethics in the sector.

This document does not include data from the following countries: Brazil, Argentina, Chile, and Ecuador due to low representativeness in the responses to the instrument used in the study.

Science and Data-Based Decision-Making Process

Regulatory decisions and decision-making must be based on scientific foundations and accurate data rather than intuition or arbitrariness. Science-based decisions provide consistent and predictable regulatory outcomes. Adherence to international standards and guidelines is a primary enabling element in science-based regulatory decision-making. The enabling elements listed above are not effective when present individually. On the contrary, these factors work in harmony in the application of good regulatory practices. For example, sufficient and sustainable financial resources contribute to the recruitment, development, and maintenance of competent human resources. Likewise, financial resources must be managed in accordance with good governance practices. *(WHO, 2022)*

Regional Overview



Graph 26.

Costa Rica leads with the best average performance **(66.7%)**, followed by Peru with an average of **64.4%**, showing notable progress in the region. Mexico holds the third position with an average of **61.3%**, while Colombia is in fourth place with an average of **46.7%**. This demonstrates that Costa Rica and Peru lead in the adoption of the "Science and Data-Based Decision-Making Process" enabler, with Mexico maintaining close proximity, while Colombia shows relatively lower performance compared to the other analyzed countries.

Reference to Consider (Good Practices from Other Countries):

Health Canada stands out for its innovative approach to evidence-based decision-making for pharmaceutical products. Its "Regulatory Innovation" program implements an agile and adaptive framework for evaluating new medicines. Additionally, they have implemented a real-time post-marketing monitoring system. Their commitment to transparency and international collaboration positions them as a global reference in evidence-based regulation Health Canada Regulatory Transparency and Openness. (Health Canada Regulatory Transparency and Openness).

Recommendations

Key recommendations to strengthen evidence-based decision-making in the analyzed countries:

- Implement robust scientific data collection and analysis systems: Develop infrastructures and tools that facilitate the collection and evaluation of relevant scientific data to support informed decisions.
- Train personnel in research and analysis methodologies: Offer training programs for staff to master advanced research and analysis techniques, which will strengthen the interpretation and use of scientific evidence.
- Incorporate scientific evidence in all stages of the regulatory process: Ensure that scientific evidence is an integral component in each phase of the regulatory process, from initial evaluation to product approval and monitoring.
- Foster a data-driven organizational culture: Promote an organizational environment where decision-making is guided by verifiable data and solid evidence.
- Promote international collaboration in best practices: Facilitate the exchange of knowledge and experiences with regulatory organizations from other countries to adopt and adapt global best practices.
- Establish standardized dossier evaluation guidelines based on international standards: Create dossier evaluation guidelines that align with international standards, thus promoting harmonization and consistency in regulatory processes.

These measures seek to align the region with international best practices.

This document does not include data from the following countries: Brazil, Argentina, Chile, and Ecuador due to low representativeness in the responses to the instrument used in the study.

7. Consolidated Analysis

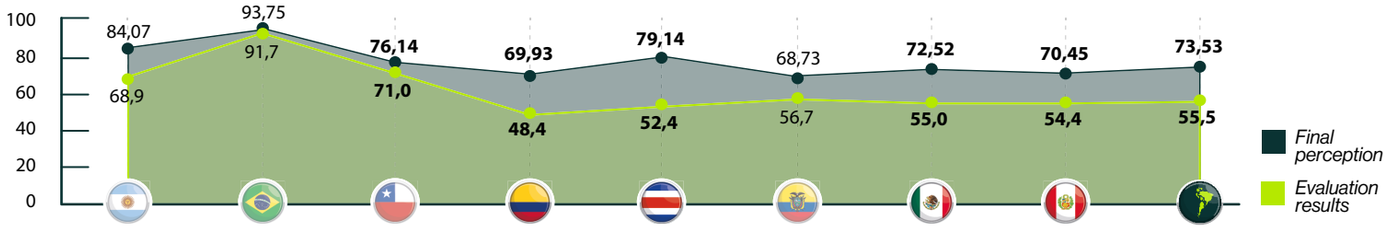
Below is a consolidated analysis of the results obtained through two complementary evaluation methodologies. First, we present the detailed findings from the survey that evaluated each principle and enabler through specific questions about their key elements, allowing for an objective measurement of the implementation level of Good Regulatory Practices (GRP) in the analyzed countries.

Second, we incorporate an analysis of participants' general perception, obtained through a direct assessment exercise at the end of the survey, where respondents used a thermometer to indicate their global perception of each principle and enabler. This dual approach allows us to contrast the detailed evaluation based on specific criteria with participants' general perception, offering a more complete view of the current state of GRP in the 8 countries

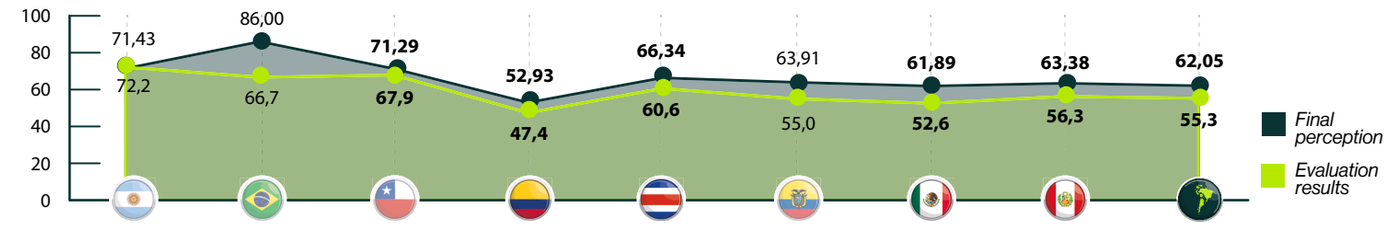
Results - Principles

Below are the results of the principles for each analyzed country.

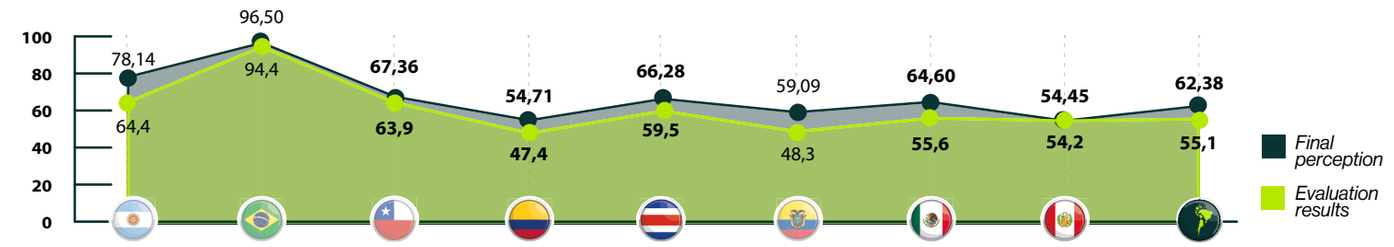
Legality



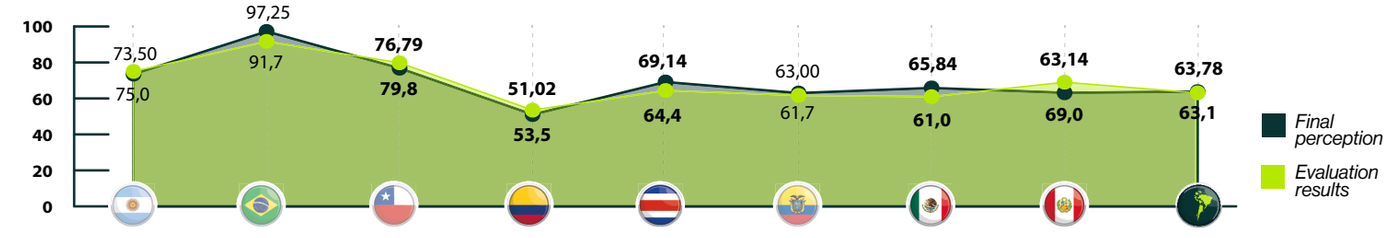
Coherence



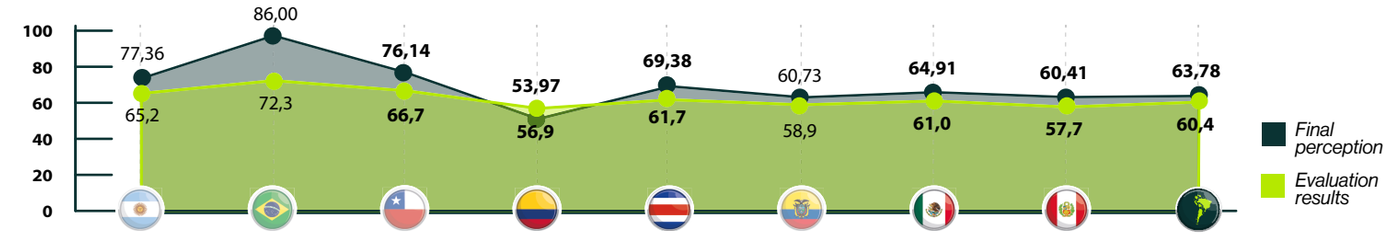
Independence



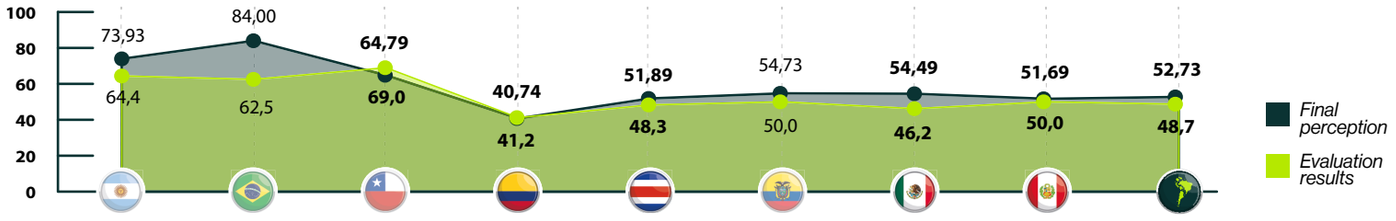
Impartiality



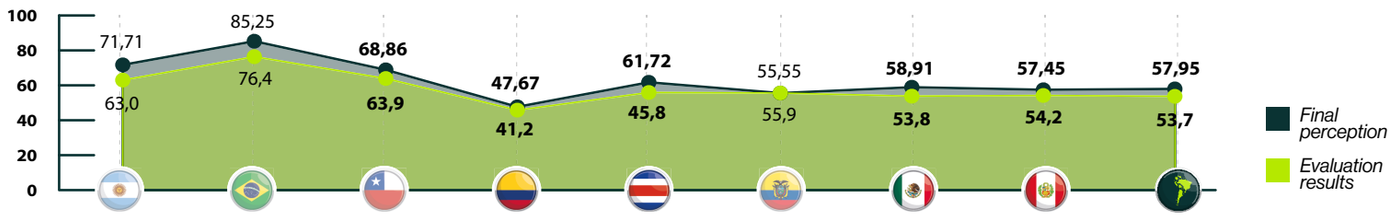
Proportionality



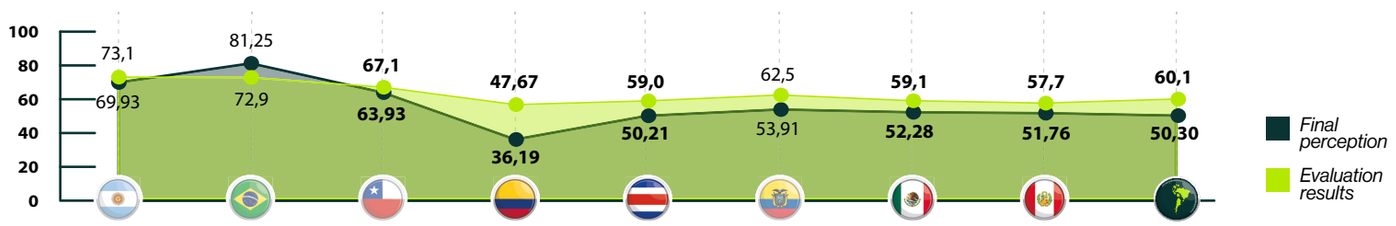
Flexibility



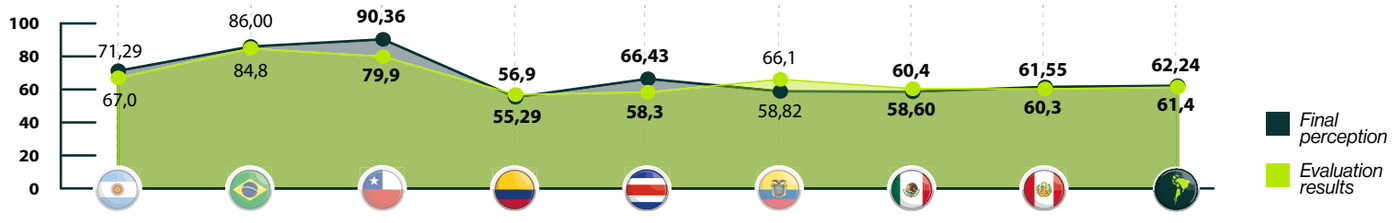
Clarity



Efficiency



Transparency



When comparing the results and final perception for GRP principles in **Colombia, Costa Rica, Mexico**, and **Peru**, some interesting discrepancies are observed.

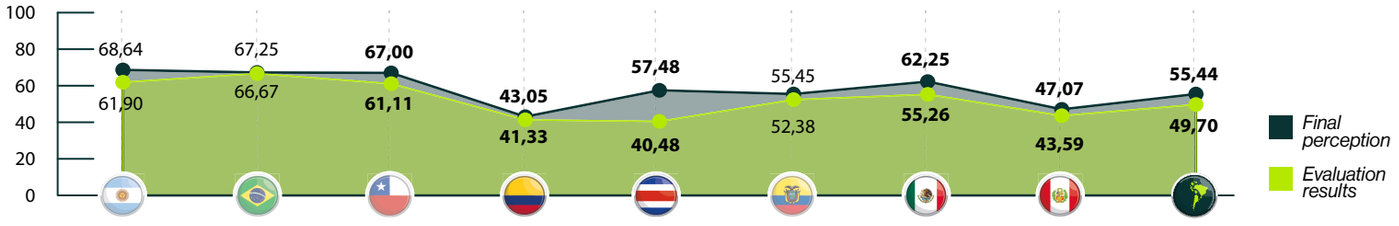
In general, perception tends to be more favorable than measured results, especially regarding the principle of legality. **Colombia** shows the most significant gap between results and perception, with notably higher perception across most principles.

Costa Rica and Mexico present less pronounced differences but still show a tendency toward more positive perception. **Peru**, on the other hand, shows closer alignment between results and perception. Across all countries, flexibility and efficiency consistently show the lowest scores in both tables, suggesting these are the aspects requiring the most attention and improvement in the region.

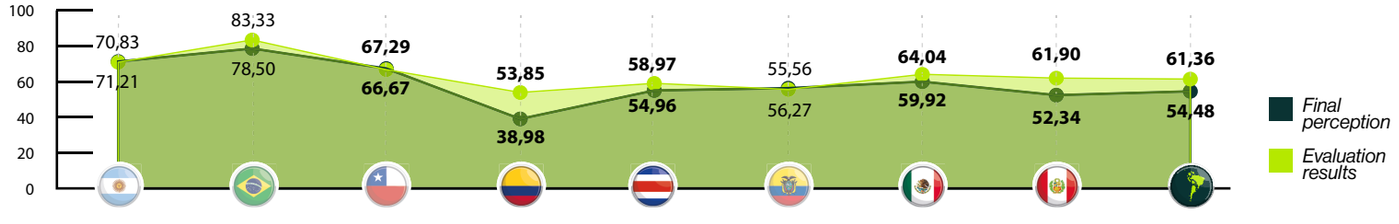
Results - Enablers

Below are the results of the principles for each analyzed country.

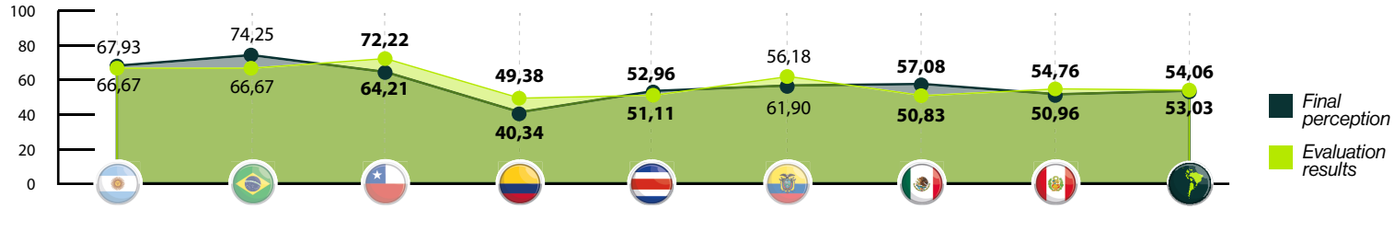
Political and whole-of-government support



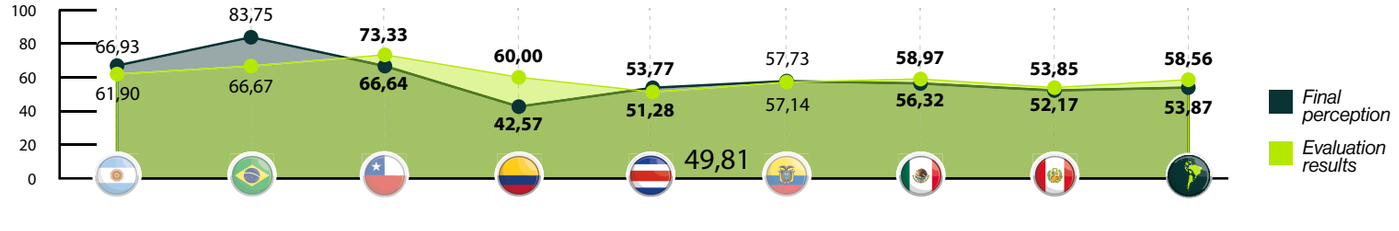
Effective organization and good governance supported through leadership



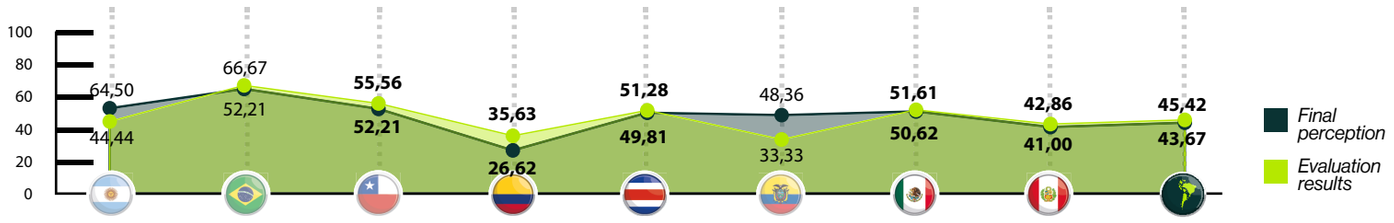
Inter-institutional and intra-institutional communication, collaboration, and coordination



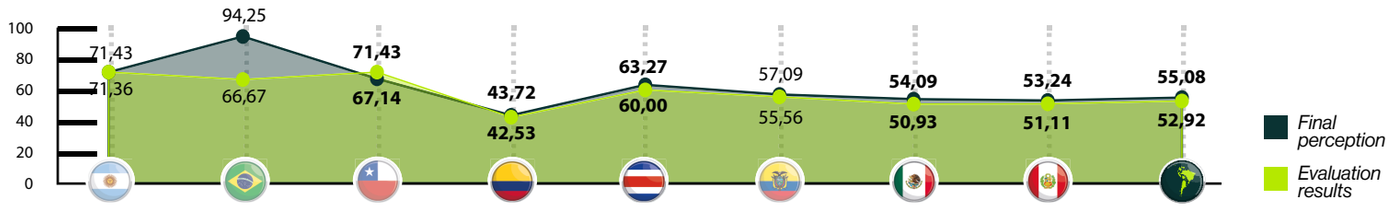
Robust quality management system



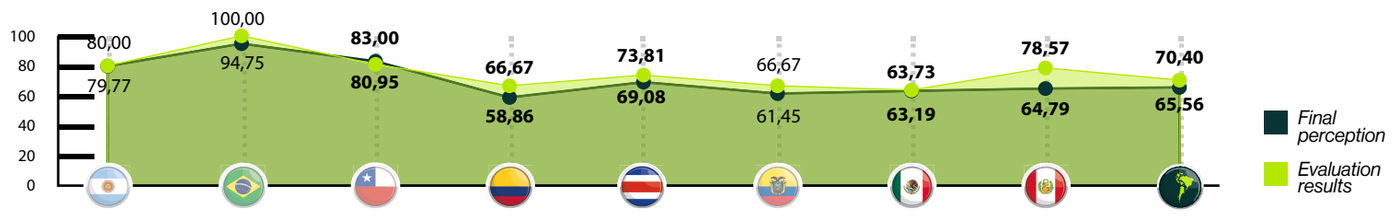
Sufficient and sustainable financial resources



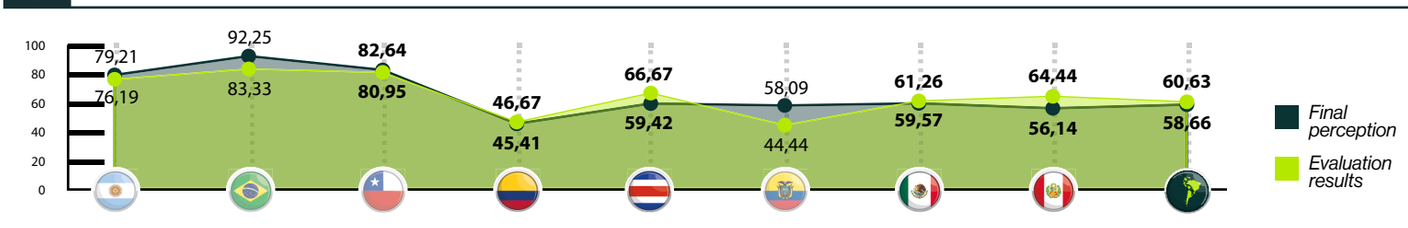
Competent Human Resources



Ethics and institutional values



Evidence-Based Decision Making



When comparing current rating results and perception of GRP enablers in Latin America, some interesting discrepancies are observed. In general, perception tends to be slightly lower than the current rating for most enablers, with some notable exceptions.

Countries like Colombia and Peru show a wider gap between current rating and perception, especially in areas such as **political support and organization and governance**. This could indicate a need to improve communication and visibility of efforts in these aspects. In the case of Costa Rica and Mexico, perception and current rating are more aligned, although there are still areas for improvement. Overall, the "**Ethics and institutional values**" enabler consistently shows high ratings in both current evaluation and perception, suggesting a regional strength in this aspect of GRP.

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in the Regulation of Pharmaceutical Products

8.

Conclusions and Recommendations

This study on the adoption of GRP in an initial group of Latin American countries has provided a comprehensive view of the current state of regulatory systems in the region, with particular focus on Colombia, Costa Rica, Mexico, and Peru. Through an exhaustive analysis of GRP principles and enablers, we have identified strengths and areas of opportunity in each evaluated country.

In this Conclusions and Recommendations section, we seek to synthesize the key findings of the study and propose concrete strategies to strengthen GRP implementation in the analyzed countries. Our objective is to offer practical and feasible suggestions that can be adopted by regulatory authorities in the region to improve the efficiency, transparency, and effectiveness of their regulatory processes.

The recommendations to be presented below are designed to address the identified gaps in areas such as flexibility, efficiency, inter-institutional synergy, and knowledge management. Additionally, strategies will be proposed to foster regional and international collaboration, with the aim of promoting a more harmonized and science-based approach in pharmaceutical product regulation.

It is important to highlight that these suggestions not only seek to improve regulatory processes themselves but also contribute to strengthening regulatory systems in the region, facilitating timely access to medicines.

8.1. Summary of Key Findings

The analysis of GRP adoption in the analyzed countries reveals significant progress in several key aspects:

Strength in legality and impartiality:
- There is a solid commitment to the legal framework and impartial decision-making in regulatory processes.

Improvement in transparency:
- There is a positive trend toward greater openness and accessibility of regulatory information.

Progress in coherence and proportionality:
- Se evidencia un esfuerzo por mantener la consistencia en las decisiones regulatorias y aplicar medidas proporcionales a los riesgos evaluados.

Advances in independence:
- Regulatory agencies show growing autonomy in their decision-making processes.

Development of technical capabilities:
- There is continuous investment in training and specialization of regulatory personnel.

Technology adoption:
- There is a trend toward implementing technological solutions to improve the efficiency of regulatory processes.

International collaboration:
- There is an increase in participation in regional and international regulatory cooperation initiatives.

These findings reflect a positive outlook, with a clear commitment to continuous improvement of regulatory systems and adoption of international GRP standards.

8.2. Conclusions

- Progress has been made, but there is still work to do: The region shows diverse advancement in the adoption of GRP principles and enablers for pharmaceutical products, but we must continue moving forward.
- WHO principles and enablers provide a powerful guiding framework for aligning efforts.
- We found no cases with significant delays.
- We found no cases with exceptional advances.
- Collaborative work between authorities and stakeholders is key to progress.
- Technology adoption is projected to be a major driver of short-term improvement.
- Authority funding is a critical aspect in the region, with commitment toward continuous improvement of regulatory systems and adoption of international GRP standards.

8.2. Recommendations to strengthen the adoption of Good Regulatory Practices in pharmaceutical product regulation

To strengthen the adoption of GRP in analyzed countries, the following actions are recommended:

Harmonization of regulatory frameworks:
- Promote the alignment of national regulations with international standards, facilitating coherence and efficiency in regulatory processes at the regional level.

Strengthening of Technical Capabilities:
- Invest in continuous training programs for regulatory personnel, focusing on key areas such as the use of regulatory decisions from other jurisdictions, pharmacovigilance, regulation of biological, biotechnological products and vaccines, risk management, and decision-making informed by benefit-risk analysis.

Implementation of digital systems:
- Adopt advanced technological platforms to streamline the submission, evaluation, and monitoring processes of pharmaceutical products, optimizing efficiency and promoting transparency.

Promotion of intersectoral collaboration:
- Establish mechanisms for dialogue and cooperation between regulatory agencies, industry, academia, and patient organizations to address regulatory challenges comprehensively.

Development of performance indicators:
- Create and implement standardized metrics to evaluate the effectiveness of GRP, enabling the identification of areas for improvement and progress monitoring.

Promotion of transparency:
- Implement information access policies that allow all stakeholders to understand and participate in regulatory processes.

Strengthening regional cooperation:
- Establish mechanisms for information and experience exchange between countries, fostering the harmonization of practices and optimization of resources.

Use of AI:
- Implement AI in GRP in Latin America to optimize regulatory processes and business models in the health sector, leveraging its transformative potential.
- Address the adoption of AI in GRP comprehensively, recognizing its efficiency opportunities while anticipating and managing ethical and governance challenges. For this, close collaboration between regulators, industry, and subject matter experts is suggested.

These recommendations seek to address the main areas of opportunity identified in the region, promoting a more efficient, transparent, and science-based approach in the regulation of pharmaceutical products.

8.3. Proposals for International and Regional Collaboration

To strengthen the adoption of GRP, the following actions are recommended:

Strengthening of the Pan American Network for Drug Regulatory Harmonization (PARF Network):

- Organize annual meetings to discuss common challenges and share best practices.

Implementation of Joint Training Programs:

- Diseñar y ejecutar programas de formación compartidos entre países para fortalecer las capacidades técnicas del personal regulatorio.Design and execute shared training programs between countries to strengthen technical capabilities of regulatory personnel.
- Promote expert exchange between regulatory agencies to facilitate knowledge transfer.

Creation of Thematic Working Groups:

- Establish multinational teams focused on specific areas such as pharmacovigilance, health technology assessment, and regulation of biotechnology products.
- Develop collaborative projects to address common regulatory challenges.

Promotion of Regulatory Harmonization:

- Identify priority regulatory functions where harmonization of regulatory requirements and processes between countries is essential.
- Implement pilot projects for regulatory reliance in pharmaceutical product evaluation and approval processes.
- Establish effective regulatory reliance mechanisms, aligning these mechanisms with WHO recommendations and international best practices

Establishment of a Regional Early Warning System:

- Create a mechanism to rapidly share information about pharmaceutical product safety and quality issues between countries.
- Develop coordinated response protocols for regional health emergencies.

Collaboration with International Organizations:

- Strengthen cooperation with entities such as WHO, PAHO, and ICH to align regional practices with international standards.
- Seek technical and financial support to implement regulatory improvement initiatives in the region.

Promotion of Collaborative Research:

- Foster joint research projects between countries on regulatory topics relevant to the region.
- Establish a regional repository of studies and data on GRP in Latin America.

This proposed course of action seeks to strengthen international and regional collaboration in GRP, promoting a more harmonized and efficient approach to pharmaceutical product regulation in the analyzed countries. The gradual implementation of these initiatives will contribute to improving the quality, safety, and access to medicines and health technologies in the region.

8.4. Strategies to improve efficiency and transparency in regulatory systems

To improve efficiency and transparency in regulatory systems, the following short, medium, and long-term strategies are proposed:

Short-term strategies (1-2 years)

- Establishment of a Regulatory Update and Harmonization Agenda: Develop a regulatory agenda for continuous review and updating of regulations and processes, aligned with international standards. This includes evaluating current regulatory requirements to improve process clarity and transparency, thus laying the foundation for future harmonization with global best practices.
- Create inter-institutional working groups to identify and eliminate redundancies in regulatory processes.
- Strengthen and diversify Authority funding mechanisms.

Medium-term strategies (3-5 years):

- Develop and implement robust quality management systems across all regulatory agencies in the region.
- Establish shared evaluation mechanisms between countries for priority pharmaceutical products, reducing duplication of efforts.
- Implement a regional pharmacovigilance and technovigilance system to improve post-marketing safety.

Long-term strategies (more than 5 years):

- Achieve active participation of Regulatory Authorities from analyzed countries in global Work-Sharing initiatives between regulators.
- Develop a regulatory personnel exchange program between countries and regions to promote knowledge transfer and best practices at regional and global levels.

These strategies seek to address the main areas of opportunity identified in the study, promoting greater efficiency, transparency, and harmonization in Latin American regulatory systems.

8.5. Importance of GRP for Public Health and Innovation in the Region

GRP are fundamental for the development of public health and innovation. Their effective implementation significantly contributes to

Ensuring the safety and efficacy of pharmaceutical products:

- GRP ensure that medicines and medical devices meet high quality standards before reaching patients.

Accelerating access to innovative treatments:

- Efficient and transparent regulatory processes enable faster evaluation of new therapies, benefiting patients who need timely access to advanced treatments.

Promoting research and development:

- A predictable and science-based regulatory environment stimulates R&D investment, promoting innovation in the pharmaceutical and medical device sector.

Improving pharmacovigilance:

- GRP strengthen post-marketing monitoring systems, enabling faster detection and response to safety issues.

Optimizing resources:

- The harmonization of regulatory practices between countries reduces duplication of efforts, allowing for more efficient allocation of resources in the health sector.

Increasing public trust:

- Transparent and evidence-based regulatory processes strengthen public confidence in health systems and available pharmaceutical products.

In summary, GRP are a fundamental pillar for the progress of health systems in Latin America, driving both the protection of public health and the advancement of medical innovation in the region.

9.

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Annexes

Principle 1. Legality

Regulatory systems and decisions derived from them must have a solid legal foundation.

The regulatory framework must provide the authority, scope, and flexibility necessary to safeguard and promote health. Which of the following options most closely resembles your regulatory health authority?

- The regulatory framework provides some authority and scope but lacks flexibility to adapt to changing needs and to effectively safeguard and promote health.
- The regulatory framework provides adequate authority and scope, with a moderate degree of flexibility to adapt to changing needs and to safeguard and promote health.
- The regulatory framework provides broad authority and scope, and shows high flexibility to adapt to changing needs, effectively safeguarding and promoting health.
- I don't have a particular opinion.

The delegation of powers and responsibilities to various levels of the regulatory system must be clear and explicit. Which of the following options most closely resembles your regulatory health authority?

- La delegación de poderes y responsabilidades a los diversos niveles del sistema regulatorio es mínimamente clara y explícita, lo que puede generar confusiones.
- La delegación de poderes y responsabilidades a los diversos niveles del sistema regulatorio es razonablemente clara y explícita, aunque podrían existir áreas de mejora.
- La delegación de poderes y responsabilidades a los diversos niveles del sistema regulatorio es altamente clara y explícita, lo que facilita un funcionamiento eficiente del sistema.
- No tengo una opinión en particular.

Regulatory frameworks must support and empower regulatory authorities to contribute to and benefit from international cooperation. Which of the following options most closely resembles your regulatory health authority?

- Regulatory frameworks offer minimal support and limited powers to regulatory authorities to contribute to international cooperation and leverage its benefits.
- Regulatory frameworks provide adequate support and sufficient powers to regulatory authorities to actively participate in international cooperation and benefit from it.
- Regulatory frameworks offer exceptional support and broad powers to regulatory authorities to lead international cooperation initiatives and maximize their benefits.
- I don't have a particular opinion.

Describe and share Good Practices and/or opportunities for improvement regarding the principle of Legality.

Systems must exist to ensure the possibility of reviewing regulatory decisions and sanctions to the regulated sector. Which of the following options most closely resembles your regulatory health authority?

- Systems exist for reviewing regulatory decisions and sanctions to the regulated sector, but they are limited and not always effective.
- Systems for reviewing regulatory decisions and sanctions to the regulated sector are present and function adequately most of the time, although there may be areas for improvement.
- Systems for reviewing regulatory decisions and sanctions to the regulated sector are robust, effective, and consistently applied in all situations.
- I don't have a particular opinion.

The regulatory framework must clearly define the scope and lines of authority of the institutions that form the regulatory system to ensure its integrity. Which of the following options most closely resembles your regulatory health authority?

- The regulatory framework defines in a limited way the scope and lines of authority of the institutions that form the regulatory system, which may compromise its integrity.
- The regulatory framework provides an adequate definition of the scope and lines of authority of the institutions that form the regulatory system, largely ensuring the system's integrity.
- The regulatory framework clearly and precisely defines the scope and lines of authority of the institutions that form the regulatory system, fully guaranteeing its integrity.
- I don't have a particular opinion.

The regulatory authority must be accountable for its actions and decisions to the public, regulated parties, and government within the framework of the law. Which of the following options most closely resembles your regulatory health authority?

- The regulatory authority offers minimal or unclear accountability for its actions and decisions to stakeholders, which may generate distrust or misunderstandings.
- The regulatory authority provides adequate and transparent accountability for its actions and decisions to stakeholders, although there could be areas to improve communication and clarity.
- The regulatory authority provides clear, complete, and transparent accountability for its actions and decisions to stakeholders, promoting trust and understanding.
- I don't have a particular opinion.

Principle 2. Coherence

Pharmaceutical product regulation should be consistent with existing government policies and legislation and be applied in a uniform and predictable manner.

The regulatory framework for pharmaceutical products must be coherently integrated into the country's legal and political framework. Which of the following options most closely resembles your regulatory health authority?

- The regulatory framework for pharmaceutical products is minimally integrated into the country's legal and political framework, which may generate inconsistencies.
- The regulatory framework for pharmaceutical products is adequately integrated into the country's legal and political framework, although there could be areas for improvement to achieve greater coherence.
- The regulatory framework for pharmaceutical products is very coherently integrated into the country's legal and political framework, ensuring effective and consistent regulation.
- I don't have a particular opinion.

New regulations must complement existing regulatory instruments and not conflict with them. Which of the following options most closely resembles your regulatory health authority?

- New regulations occasionally complement existing regulatory instruments but sometimes conflict with them, generating inconsistencies.
- Most new regulations occasionally complement existing regulatory instruments and rarely conflict with them, although there could be areas for improvement.
- All new regulations effectively complement existing regulatory instruments and never conflict with them, ensuring complete coherence.
- I don't have a particular opinion.

Regulatory requirements must be applied and enforced consistently across all pharmaceutical industry sectors and stakeholders. Which of the following options most closely resembles your regulatory health authority?

- - Regulatory requirements are inconsistently applied and enforced across all pharmaceutical industry sectors and stakeholders, which can lead to irregularities and lack of uniformity.
- - Regulatory requirements are fairly consistently applied and enforced across all pharmaceutical industry sectors and stakeholders. There is an adequate level of coherence, although there may be areas for improvement.
- - Regulatory requirements are extremely consistently applied and enforced across all pharmaceutical industry sectors and stakeholders, ensuring total coherence and uniformity.
- - I don't have a particular opinion.

Describe and share Good Practices and/or opportunities for improvement regarding the principle of Coherence.

Principle 3. Independence

Institutions responsible for regulating pharmaceutical products must be independent.

The regulatory system must function, and must be seen to function, independently, exercising its functions independently of politicians and government. Which of the following options most closely resembles your regulatory health authority?

- The regulatory system sometimes functions independently, but there are times when it is subject to positions or directives from politicians and government, compromising its independence.
- The regulatory system generally functions independently, although there are occasions when politicians and government can impose their positions or directives on the regulator.
- The regulatory system always functions independently and carries out its functions without any position or directive from politicians and government.
- I don't have a particular opinion.

Regulatory activities and decisions must be free from undue and improper influences from stakeholders. Which of the following options most closely resembles your regulatory health authority?

- Regulatory activities and decisions are often subject to undue and improper influences from stakeholders, which may compromise the independence and impartiality of the regulatory process.
- Regulatory activities and decisions are generally free from undue and improper influences, although there are situations where stakeholders may exert some influence.
- Regulatory activities and decisions are completely free from undue and improper influences from stakeholders, ensuring an impartial and transparent regulatory process.
- I don't have a particular opinion.

Sufficient funding and clear financing mechanisms are essential. Which of the following options most closely resembles your regulatory health authority?

- Funding and financing mechanisms are insufficient and ambiguous, making effective operation of the regulatory system difficult.
- Funding and financing mechanisms are adequate but could be improved to more effectively support the regulatory system.
- Funding is abundant and financing mechanisms are clear, enabling efficient and effective operation of the regulatory system.
- I don't have a particular opinion.

The independence of leaders must be established to ensure independent behavior during the fulfillment of their duties and upon leaving that employment. Which of the following options most closely resembles your regulatory health authority?

- Leaders' independence is partially established, although there are situations where their behavior may be influenced during the fulfillment of their duties and upon leaving that employment.
- Leaders' independence is mostly established and generally ensures independent behavior during the fulfillment of their duties and upon leaving that employment, although there could be areas for improvement.
- Leaders' independence is fully established and ensures completely independent behavior during the fulfillment of their duties and upon leaving that employment.
- I don't have a particular opinion.

Describe and share Good Practices and/or opportunities for improvement regarding the principle of Independence.

Principle 4. Impartiality

All parties must receive equitable, fair, and impartial treatment.

Regulatory activities and decisions must be free from conflicts of interest or improper bias. Which of the following options most closely resembles your regulatory health authority?

- Regulatory activities and decisions are often subject to conflicts of interest and improper bias, which may compromise the transparency and fairness of the regulatory process.
- Regulatory activities and decisions are generally free from conflicts of interest and improper bias, although there are situations where certain conflicts and biases may be present.
- Regulatory activities and decisions are completely free from conflicts of interest and improper bias, ensuring a transparent and equitable regulatory process.
- I don't have a particular opinion.

The regulatory system must operate with impartiality. Which of the following options most closely resembles your regulatory health authority?

- The regulatory system sometimes operates with impartiality, but there are situations where influences or biases may be seen, which compromises the fairness of the process.
- The regulatory system generally operates with impartiality, although there are times when certain biases or influences may be observed.
- The regulatory system always operates with complete impartiality, without any influences or biases, ensuring a fair and equitable regulatory process.
- I don't have a particular opinion.

Describe and share Good Practices and/or opportunities for improvement regarding the principle of Impartiality.

It is essential to have sufficient funding and clear mechanisms for The regulatory authority must not participate in the activities it regulates nor be in a hierarchically subordinate position to the institutions that carry out the regulated activities. Which of the following options most closely resembles your regulatory health authority?

- The regulatory authority often participates in the activities it regulates and/or is in a hierarchically subordinate position to the institutions that carry out the regulated activities, which may compromise its independence and objectivity.
- The regulatory authority generally does not participate in the activities it regulates and is not in a hierarchically subordinate position to the institutions that carry out the regulated activities, although there may be exceptions or gray areas.
- The regulatory authority never participates in the activities it regulates and always maintains a hierarchically independent position from the institutions that carry out the regulated activities, ensuring its total independence and objectivity.
- I don't have a particular opinion.

Regulatory decisions must be based on science and evidence, and the decision-making process must be robust, following defined criteria. Which of the following options most closely resembles your regulatory health authority?

- Regulatory decisions are sometimes based on science and evidence, but the decision-making process is not always robust or following defined criteria, which can lead to inconsistent or arbitrary decisions.
- Regulatory decisions are generally based on science and evidence, and the decision-making process is mostly robust and follows defined criteria, although there is room to improve consistency and transparency.
- Regulatory decisions are always based on science and evidence, and the decision-making process is robust, transparent, and always follows defined criteria, ensuring consistent and fair decisions.
- I don't have a particular opinion.

Principle 5. Proportionality

Regulatory oversight (regulatory enforcement and decisions) must be proportional to the risk and regulators' capacity to implement and enforce them.

Regulation must be adequate to achieve objectives without being excessively burdensome. Which of the following options most closely resembles your national regulatory authority?

- Regulation is minimal, which may limit its ability to effectively achieve objectives.
- Regulation is adequate, allowing objectives to be achieved but can be improved.
- Regulation is comprehensive and precise, optimizing the achievement of objectives.
- I don't have a particular opinion.

The evaluation of pharmaceutical products must be based on an assessment of risks and benefits and continuous monitoring of the risk-benefit profile in a robust surveillance system. Which of the following options most closely resembles your regulatory health authority?

- The evaluation of pharmaceutical products is occasionally based on an assessment of risks and benefits and continuous monitoring of the risk-benefit profile in a surveillance system, although the latter may not be robust, which can compromise the quality of the evaluation.
- The evaluation of pharmaceutical products is generally based on an assessment of risks and benefits and continuous monitoring of the risk-benefit profile in a robust surveillance system, although there may be room to improve the consistency and rigor of the evaluation.
- The evaluation of pharmaceutical products is always based on a rigorous assessment of risks and benefits and continuous monitoring of the risk-benefit profile in a robust surveillance system, ensuring accurate and high-quality evaluations.
- I don't have a particular opinion.

Regulations must not exceed national capacity to implement and enforce them. Which of the following options most closely resembles your regulatory health authority?

- Regulations often exceed national capacity to implement and enforce them, which can lead to low compliance and implementation difficulties.
- Regulations generally align with national capacity to implement and enforce them, although in some cases they may be challenging to implement.
- Regulations are always aligned with national capacity to implement and enforce them, ensuring effective implementation and a high level of compliance.
- I don't have a particular opinion.

Regulatory Impact Assessment (RIA) is a public policy tool aimed at ensuring the quality of regulations and that benefits exceed costs. How frequently do NRAs use RIA?

- Never.
- Generally.
- Always.
- I don't know / I'm not familiar.

Describe and share Good Practices and/or opportunities for improvement regarding the principle of Proportionality.

Principle 6. Flexibility

Regulatory oversight (enforcement) must be flexible to respond to a changing environment and unforeseen circumstances.

The regulatory system, including its frameworks, must provide sufficient flexibility to reflect or respond to changes in the regulated environment, such as the continuous evolution of science and technology. Which of the following options most closely resembles your regulatory health authority?

- The regulatory system offers some flexibility to reflect or respond to changes in the regulated environment, but often lags behind in adapting to the continuous evolution of science and technology.
- The regulatory system generally provides flexibility to reflect or respond to changes in the regulated environment and closely follows the evolution of science and technology, although there may be some delays or difficulties in adapting to rapid changes.
- The regulatory system is highly flexible and quickly adapts to reflect or respond to any changes in the regulated environment, keeping pace with the continuous evolution of science and technology.
- I don't have a particular opinion.

The regulatory system must be prepared to provide timely responses to urgent situations such as public health emergencies and shortages of pharmaceutical products. Which of the following options most closely resembles your regulatory health authority?

- The regulatory system has difficulties providing timely responses to urgent situations such as public health emergencies and shortages of pharmaceutical products, which may compromise the effectiveness of the response.
- The regulatory system can generally provide timely responses to urgent situations, such as public health emergencies and shortages of pharmaceutical products, although there may be some delays or difficulties in certain situations.
- The regulatory system is always prepared to provide timely and effective responses to urgent situations, such as public health emergencies and shortages of pharmaceutical products, ensuring an effective response at all times.
- I don't have a particular opinion.

The regulatory system must provide the necessary regulatory flexibility to interpret existing legislation and regulations appropriately. Which of the following options most closely resembles your national regulatory authority?

- The regulatory system provides limited regulatory flexibility to interpret existing legislation and regulations appropriately.
- The regulatory system provides adequate regulatory flexibility to interpret existing legislation and regulations appropriately but there is room for improvement.
- The regulatory system provides extensive regulatory flexibility to interpret existing legislation and regulations appropriately.
- I don't have a particular opinion.

Describe and share Good Practices and/or opportunities for improvement regarding the principle of Flexibility.

Principle 7. Clarity

Regulatory requirements must be accessible to users and understood by them.

Consultation, education, and training on new requirements contribute to clarification and compliance. Which of the following options most closely resembles your regulatory health authority?

- There are some consultations, educational and training programs on new requirements, but they are limited or not effectively implemented, which can hinder the clarification and compliance with requirements.
- Consultations, education, and training on new requirements are conducted adequately and regularly, contributing to the clarification and compliance with requirements, although there could be areas for improvement.
- There are well-structured and comprehensive consultations, educational and training programs on new requirements that are implemented effectively and regularly, ensuring optimal clarification and compliance with requirements.
- I don't have a particular opinion.

Guidelines and orientation guides are fundamental for the proper interpretation of regulations. Which of the following options most closely resembles your regulatory health authority?

- Guidelines and orientation guides are present but limited or unclear, which can make proper interpretation of regulations difficult.
- Guidelines and orientation guides are adequate and provide useful guidance, but could be more detailed or specific to facilitate better interpretation of regulations.
- Guidelines and orientation guides are comprehensive, clear, and specific, facilitating accurate and effective interpretation of regulations.
- I don't have a particular opinion

The process and basis for adopting regulatory decisions and measures to obtain compliance must be clear. Which of the following options most closely resembles your regulatory health authority?

- The process and basis for adopting regulatory decisions and compliance measures are vaguely defined and can be difficult to interpret, which may generate uncertainty.
- The process and basis for adopting regulatory decisions and compliance measures are reasonably clear, although there may be areas of ambiguity that could be clarified.
- The process and basis for adopting regulatory decisions and compliance measures are extremely clear and concise, facilitating their understanding and application.
- I don't have a particular opinion.

Regulatory instruments must be written in a way that users can understand. Which of the following options most closely resembles your national regulatory authority?

- Regulatory instruments are written in a way that users can understand to some extent, but it is often complex and difficult to interpret, which can generate confusion.
- Regulatory instruments are written in a way that users can generally understand, although there could be room to improve the clarity and simplicity of the language.
- Regulatory instruments are always written in a way that users can easily understand, being clear, simple, and direct, which facilitates complete understanding.
- I don't have a particular opinion.

Regulations are aligned with international standards without adding additional requirements when not necessary. Which of the following options most closely resembles your national regulatory authority?

- - Only in some cases are regulations aligned with international standards without adding additional requirements when not necessary.
- - Most of the time, regulations are aligned with international standards without adding additional requirements when not necessary.
- - Regulations are aligned with international standards without adding additional requirements when not necessary.
- - I don't have a particular opinion.

Describe and share Good Practices and/or opportunities for improvement regarding the principle of Clarity.

Principle 8. Efficiency

Regulatory systems must achieve their objectives within the required timeframe and with reasonable effort and cost.

Efficient regulatory systems achieve intended public health objectives. Which of the following options most closely resembles your regulatory health authority?

- Regulatory systems achieve intended public health objectives partially or inconsistently, which can limit their effectiveness.
- Regulatory systems generally achieve intended public health objectives, although there could be room to improve effectiveness and consistency.
- Regulatory systems always achieve intended public health objectives effectively and consistently, demonstrating high efficiency.
- I don't have a particular opinion.

A solid regulatory framework, competent staff, and effective use of resources and information from other authorities are key elements of an efficient regulatory system. Which of the following options most closely resembles your regulatory health authority?

- The regulatory framework is weak and staff have limited competencies. The use of resources and information from other authorities is scarce or ineffective, which limits the efficiency of the regulatory system.
- The regulatory framework is solid and staff are competent, but there is room for improvement. The use of resources and information from other authorities is adequate but could be optimized to improve the efficiency of the regulatory system.
- The regulatory framework is solid and robust, staff are highly competent, and resources and information from other authorities are used effectively. These key elements ensure a highly efficient regulatory system.
- I don't have a particular opinion.

Regulatory authorities must continuously explore ways to improve efficiency in fulfilling their mandate. Which of the following options most closely resembles your regulatory health authority?

- Regulatory authorities rarely seek ways to improve efficiency in fulfilling their mandate, which can limit the overall effectiveness of the regulatory system.
- Regulatory authorities often seek ways to improve efficiency in fulfilling their mandate, although there could be room for more systematic exploration and implementation of these improvements.
- Regulatory authorities are always exploring and implementing new ways to improve efficiency in fulfilling their mandate, ensuring optimal effectiveness and efficiency in their regulatory work.
- I don't have a particular opinion.

International convergence efforts, such as ICH (International Conference on Harmonization) guidelines, have been fully implemented. Which of the following options most closely resembles your national regulatory authority?

- International convergence efforts, such as ICH guidelines, have not been implemented.
- International convergence efforts, such as ICH guidelines, have been partially implemented.
- International convergence efforts, such as ICH guidelines, have been fully implemented.
- I don't have a particular opinion

Policy makers must seek the most efficient and least burdensome means of achieving their regulatory objectives and confirm effectiveness after implementation. Which of the following options most closely resembles your regulatory health authority?

- Policy makers occasionally seek the most efficient and least burdensome means to achieve their regulatory objectives, but confirmation of effectiveness after implementation is inconsistent or not performed, which may compromise regulatory effectiveness.
- Policy makers generally seek the most efficient and least burdensome means to achieve their regulatory objectives and usually confirm effectiveness after implementation. However, there may be room to improve the consistency and rigor of these efforts.
- Policy makers always seek the most efficient and least burdensome means to achieve their regulatory objectives and always confirm effectiveness after implementation. This systematic and rigorous approach ensures maximum regulatory effectiveness.
- I don't have a particular opinion.

There are alternative proposals to existing regulatory policies to achieve expected results with reasonable efforts and costs

- The regulated sector has never developed alternative proposals or initiatives to existing regulatory policies.
- The regulated sector has attempted to develop alternative proposals or initiatives to existing regulatory policies but they have not been implemented
- The regulated sector has developed and implemented alternative proposals or initiatives to existing regulatory policies.
- I don't have a particular opinion.

Describe and share Good Practices and/or opportunities for improvement regarding the principle of Efficiency.

The regulated sector (industry) makes an important contribution to the efficiency of regulatory systems. Which of the following options most closely resembles your regulatory health authority?

- The regulated sector (industry) occasionally contributes to the efficiency of regulatory systems, although their participation may be limited or inconsistent, which can impact the overall effectiveness of the system.
- The regulated sector (industry) often contributes to the efficiency of regulatory systems, although there could be room for greater engagement and cooperation from these entities.
- The regulated sector (industry) always actively contributes to the efficiency of regulatory systems, demonstrating continuous commitment and effective cooperation that maximizes the effectiveness of regulatory systems.
- I don't have a particular opinion

The implementation and efficiency of regulations are regularly monitored and evaluated. Which of the following options most closely resembles your national regulatory authority?

- The implementation and efficiency of regulations are occasionally monitored and evaluated.
- The implementation and efficiency of regulations are generally monitored and evaluated.
- The implementation and efficiency of regulations are always monitored and evaluated.
- I don't have a particular opinion

There are alternative proposals to existing regulatory policies to achieve expected results with reasonable efforts and costs

- The regulated sector has never developed alternative proposals or initiatives to existing regulatory policies.
- The regulated sector has attempted to develop alternative proposals or initiatives to existing regulatory policies but they have not been implemented.
- The regulated sector has developed and implemented alternative proposals or initiatives to existing regulatory policies.
- I don't have a particular opinion.

Principle 9. Transparency

Transparency is the hallmark of a well-functioning regulatory system and is essential for fostering public trust and promoting international cooperation.

Transparency requires investment and a culture of openness, supported by policy, commitment, and government action. Which of the following options most closely resembles your regulatory health authority?

- Transparency is occasionally promoted through a culture of openness, but there may be inconsistencies and lack of political support, commitment, and government action, which can limit its effectiveness.
- Transparency is mostly promoted through a culture of openness, supported by policy, commitment, and government action, although there could be room for greater coherence and support.
- Transparency is always promoted through a culture of openness, consistently and solidly supported by policy, commitment, and government action, which ensures its effectiveness.
- I don't have a particular opinion.

The national regulatory authority provides responses and adopts relevant comments submitted in a public consultation process. Which of the following options most closely resembles your national regulatory authority?

- The national health authority does not provide responses and does not adopt relevant comments submitted in a public consultation process.
- The national health authority sometimes provides responses and adopts relevant comments submitted in a public consultation process.
- The national health authority always provides responses and adopts relevant comments submitted in a public consultation process.
- I don't have a particular opinion.

Describe and share Good Practices and/or opportunities for improvement regarding the principle of Transparency

- **In your opinion, what is the level of development of each principle in your country's authority agency?** place your rating from 0 to 100 on the following thermometer 1. Legality
- **In your opinion, what is the level of development of each principle in your country's authority agency?** place your rating from 0 to 100 on the following thermometer 2. Coherence
- **In your opinion, what is the level of development of each principle in your country's authority agency?** place your rating from 0 to 100 on the following thermometer 3. Independence
- **In your opinion, what is the level of development of each principle in your country's authority agency?** place your rating from 0 to 100 on the following thermometer 4. Impartiality
- **In your opinion, what is the level of development of each principle in your country's authority agency?** place your rating from 0 to 100 on the following thermometer 5. Proportionality
- **In your opinion, what is the level of development of each principle in your country's authority agency?** place your rating from 0 to 100 on the following thermometer 6. Flexibility
- **In your opinion, what is the level of development of each principle in your country's authority agency?** place your rating from 0 to 100 on the following thermometer 7. Clarity
- **In your opinion, what is the level of development of each principle in your country's authority agency?** place your rating from 0 to 100 on the following thermometer 8. Efficiency
- **In your opinion, what is the level of development of each principle in your country's authority agency?** place your rating from 0 to 100 on the following thermometer 9. Transparency

Regulatory requirements, processes, fees, assessments, decisions, and actions should be as accessible as possible. Which of the following options most closely resembles your regulatory health authority?

- Regulatory requirements, processes, fees, assessments, decisions, and actions are usually accessible, but there may be limitations or barriers that hinder access, which can affect transparency and regulatory effectiveness.
- Regulatory requirements, processes, fees, assessments, decisions, and actions are generally accessible and most barriers have been eliminated, although there may still be room to improve accessibility and transparency.
- Regulatory requirements, processes, fees, assessments, decisions, and actions are always highly accessible and all barriers have been eliminated, ensuring maximum transparency and regulatory effectiveness.
- I don't have a particular opinion.

Las políticas de la autoridad regulatoria con respecto a la divulgación de información de carácter pública deben ser coherentes con las legislaciones nacionales sobre el acceso a la información. ¿Cuál de las siguientes opciones se asemeja más a su autoridad sanitaria reguladora?

- The regulatory authority's policies regarding public information disclosure are only occasionally consistent with national legislation on access to information, which creates inconsistencies and lack of transparency.
- The regulatory authority's policies regarding public information disclosure are generally consistent with national legislation on access to information, but there could be certain situations where consistency could improve.
- The regulatory authority's policies regarding public information disclosure are always consistent with national legislation on access to information, ensuring total transparency and coherence.
- I don't have a particular opinion.

The national regulatory authority provides responses and adopts relevant comments submitted in a public consultation process. Which of the following options most closely resembles your national regulatory authority?

- The national health authority does not provide responses and does not adopt relevant comments submitted in a public consultation process.
- The national health authority sometimes provides responses and adopts relevant comments submitted in a public consultation process.
- The national health authority always provides responses and adopts relevant comments submitted in a public consultation process.
- I don't have a particular opinion.

Enabler 1. Political and whole-of-government support

Sustained support from the highest political and governmental levels, including policymakers, is essential for the proper application of good regulatory practices concepts and principles. These good practices must be an integral part of all government policies on regulatory systems and have strong political support. Which of the following options most closely resembles your regulatory health authority?

- Support from the highest political and governmental levels for implementing good regulatory practices is occasional and fluctuating. Good regulatory practices are not considered an integral part of all government policies and political backing is weak.
- There is general support from the highest political and governmental levels for implementing good regulatory practices, although it may be inconsistent. Good regulatory practices are part of most government policies and political support is moderate.
- Sustained support from the highest political and governmental levels for implementing good regulatory practices is constant and solid. Good regulatory practices are an integral part of all government policies and political support is firm and constant.
- I don't have a particular opinion.

Investment in a regulatory system is fundamental for the proper functioning of a healthcare system. Having sufficient financial resources to effectively fulfill its regulatory mandate and continuously improve the performance of regulatory activities is essential for the independence, impartiality, coherence, and efficiency of a regulatory system. Which of the following options most closely resembles your regulatory health authority?

- Investment in the regulatory system is minimal and financial resources are insufficient. This limits the system's ability to effectively fulfill its regulatory mandate and improve its performance.
- Investment in the regulatory system is adequate and financial resources are sufficient to fulfill the regulatory mandate, but there are limitations in the ability to continuously improve performance.
- Investment in the regulatory system is robust and financial resources are ample, enabling effective fulfillment of the regulatory mandate and continuous performance improvement.
- I don't have a particular opinion.

Describe and share Good Practices and/or opportunities for improvement regarding the enabler of Sufficient and sustainable financial resources.

Enabler 2. Effective organization and good governance supported through leadership

The structure and line of authority between and within all institutions in the regulatory system must be well defined. The integrity of the overall regulatory system is fundamental to the efficient performance of each of its constituent institutions. If more than one institution participates in the regulatory system, legislation or institutional regulation must provide for clear coordination without overlap of regulatory activities. Which of the following options most closely resembles your regulatory health authority?

- The structure and line of authority between and within all institutions in the regulatory system are vaguely defined. The integrity of the overall regulatory system may be weak, affecting the efficiency of each of its constituent institutions.
- The structure and line of authority between and within all institutions in the regulatory system are reasonably defined. The integrity of the overall regulatory system is adequate, contributing to the efficiency of each of its constituent institutions.
- The structure and line of authority between and within all institutions in the regulatory system are clearly defined. The integrity of the overall regulatory system is solid, ensuring a high level of efficiency among all its constituent institutions.
- I don't have a particular opinion.

Describe and share Good Practices and/or opportunities for improvement regarding the enabler of Effective organization and good governance supported through leadership.

A range of technical and scientific knowledge and skills of regulatory personnel contribute to the development, implementation, and maintenance of an effective regulatory system for pharmaceutical products. Personnel and professional development policies and measures (e.g., training programs, competitive compensation schemes) are fundamental for regulatory authorities to attract and retain competent staff in service. Which of the following options most closely resembles your regulatory health authority?

- Regulatory personnel possess some necessary technical and scientific knowledge and skills, but these may be limited or inconsistent. Existing personnel and professional development policies and measures are minimal and insufficient to attract and retain competent staff.
- Regulatory personnel possess a good amount of the required technical and scientific knowledge and skills. Personnel and professional development policies and measures are present and have a moderate impact on attracting and retaining competent staff.
- Regulatory personnel possess a high level of technical and scientific knowledge and skills necessary for the work. Personnel and professional development policies and measures are strong, effective, and result in high attraction and retention of competent staff.
- I don't have a particular opinion

Describe and share Good Practices and/or opportunities for improvement regarding the enabler of Competent human resources.

Enabler 3. Inter-institutional and intra-institutional communication, collaboration, and coordination

Adequate and effective communication plays a fundamental role in the exchange of information within and outside the institutions that make up the regulatory system. When regulatory authorities communicate regularly, both internally and externally, they remain more transparent and accountable. Communicating correct information prevents potential misunderstandings and the spread of misleading information to patients and the public. Which of the following options most closely resembles your regulatory health authority?

- Communication within and outside the institutions that make up the regulatory system is limited or inconsistent. Transparency and accountability may be deficient due to lack of regular communication.
- Communication within and outside the institutions that make up the regulatory system is adequate, but there may be room for improvement. Transparency and accountability are generally good, but may be inconsistent.
- Communication within and outside the institutions that make up the regulatory system is excellent and is carried out regularly and effectively. Transparency and accountability are high, and information is always accurate, preventing the spread of misleading information to patients and the public.
- I don't have a particular opinion.

Describe and share Good Practices and/or opportunities for improvement regarding the enabler of Inter-institutional and intra-institutional communication, collaboration, and coordination.

Regulatory personnel must comply with the institution's principles and ethical values and demonstrate professionalism. All regulatory personnel must know and receive training on the regulatory authority's ethical principles and values (for example, a code of conduct). A system must be established, within or outside the regulatory system, to manage deviations from institutional ethics and values. Which of the following options most closely resembles your regulatory health authority?

- Regulatory personnel have limited knowledge and understanding of the regulatory authority's principles and ethical values.
- Regulatory personnel have good knowledge and understanding of the regulatory authority's principles and ethical values, although there may be room for deeper and more consistent training.
- Regulatory personnel have deep knowledge and clear understanding of the regulatory authority's principles and ethical values and receive regular and consistent training in these aspects.
- I don't have a particular opinion.

Describe and share Good Practices and/or opportunities for improvement regarding the enabler of Ethics and institutional values.

Enabler 4. A robust, well-functioning quality management system

A quality management system, which includes the application of quality risk management principles, makes regulatory authorities' decisions more credible and their operations more stable and consistent. A quality management system contributes to systematic planning, control, and quality improvement across all regulatory function processes and ensures a comprehensive approach. Which of the following options most closely resembles your regulatory health authority?

- The quality management system is minimal and has deficiencies. The application of quality risk management principles is irregular, which may affect the credibility of regulatory authorities' decisions and the stability of their operations.
- The quality management system is present and functional, but with room for improvement. Quality risk management principles are mostly applied, supporting the credibility of regulatory authorities' decisions and the stability of their operations.
- The quality management system is robust, comprehensive, and effective. Quality risk management principles are applied consistently and comprehensively, strengthening the credibility of regulatory authorities' decisions and the stability of their operations.
- I don't have a particular opinion

Describe and share Good Practices and/or opportunities for improvement regarding the enabler of a robust, well-functioning quality management system.

Regulatory decisions and decision-making must be based on scientific foundations and accurate data, not intuition or arbitrariness. Science-based decisions provide consistent and predictable regulatory outcomes. Adherence to international standards and guidelines is a fundamental enabler in science-based regulatory decision-making.

- Regulatory decisions and decision-making are occasionally based on scientific foundations and accurate data, but this approach may be inconsistent. Adherence to international standards and guidelines is limited.
- Regulatory decisions and decision-making are generally based on scientific foundations and accurate data. There is general adherence to international standards and guidelines.
- Regulatory decisions and decision-making are always based on scientific foundations and accurate data. There is complete adherence to international standards and guidelines.
- I don't have a particular opinion.

Describe and share Good Practices and/or opportunities for improvement regarding the enabler of Science and data-driven decision-making process.

- **In your opinion, what is the level of development of each enabler in your country's authority agency?** Place your rating from 0 to 100 on the following thermometer 1. Political and whole-of-government support
- **In your opinion, what is the level of development of each enabler in your country's authority agency?** Place your rating from 0 to 100 on the following thermometer 2. Effective organization and good governance supported through leadership.
- **In your opinion, what is the level of development of each enabler in your country's authority agency?** Place your rating from 0 to 100 on the following thermometer 3. Inter-institutional and intra-institutional communication, collaboration, and coordination.
- **In your opinion, what is the level of development of each enabler in your country's authority agency?** Place your rating from 0 to 100 on the following thermometer 4. A robust, well-functioning quality management system.
- **In your opinion, what is the level of development of each enabler in your country's authority agency?** Place your rating from 0 to 100 on the following thermometer 5. Sufficient and sustainable financial resources.
- **In your opinion, what is the level of development of each enabler in your country's authority agency?** Place your rating from 0 to 100 on the following thermometer 6. Competent human resources.
- **In your opinion, what is the level of development of each enabler in your country's authority agency?** Place your rating from 0 to 100 on the following thermometer 7. Ethics and institutional values.
- **In your opinion, what is the level of development of each enabler in your country's authority agency?** Place your rating from 0 to 100 on the following thermometer 8. Science and data-driven decision-making process.

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