

Regulatory Diplomacy in American Regional Organizations and Mechanisms: Towards a Regional Health Self-sufficiency

Diplomacia regulatoria en los organismos y mecanismos regionales americanos: hacia la autosuficiencia sanitaria regional

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Abstract

Mexico has assumed a leadership position within the framework of regional organizations and mechanisms in order to promote health self-sufficiency in Latin America and the Caribbean. As Pro Tempore President of CELAC, Mexico led the adoption of a Health Self-sufficiency Plan for the region. This Plan includes the promotion of a regional medicine's agency and the installation of a regional school of sanitary regulation. At the hemispheric level, it has promoted the agenda of the Pan American Health Organization, been the host of the XI Conference of the Pan American Network on Drug Regulatory Harmonization.



Resumen

México ha asumido una posición de liderazgo en el seno de los organismos y mecanismos regionales a fin de promover la autosuficiencia sanitaria en América Latina y el Caribe. En el marco de la Comunidad de Estados Latinoamericanos y Caribeños lideró la adopción de un plan de autosuficiencia sanitaria para la región, de la cual han derivado proyectos como la construcción de una agencia latinoamericana y caribeña de medicamentos, así como la instalación de una escuela regional de regulación sanitaria. En el plano hemisférico, ha impulsado la agenda de la Organización Panamericana de la Salud, siendo sede de la XI Conferencia Panamericana para la Armonización de la Reglamentación Farmacéutica.



Keywords

Health Self-sufficiency, regulatory harmonization, Community of Latin American and Caribbean States, Pan American Health Organization



Palabras clave

Autosuficiencia sanitaria, armonización regulatoria, Comunidad de Estados Latinoamericanos y Caribeños, Organización Panamericana de la Salud.

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Introduction

In a global context marked by unprecedented health challenges, Mexico has emerged as a leader in Latin America and the Caribbean in promoting self-sufficiency in health. Its commitment to public health has expressed itself in initiatives aimed at strengthening cooperation and ensuring equitable access to medical services, medicines, and sanitary technologies. The leading participation of Mexico in international organizations such as the World Health Organization (WHO) and the Pan American Health Organization (PAHO) reflects its active role in defending global health standards, promoting the right to universal health and the implementation of effective response strategies for health emergencies.

Mexican leadership has been shown in the implementation of crucial regional projects, such as the Plan for Self-sufficiency in Health Matters for Latin America and the Caribbean (PAS) of the Economic Commission for Latin America and the Caribbean (ECLAC), the Latin American and Caribbean Medicines and Medical Devices Regulatory Agency (AMLAC) and the Regional School for Sanitary Regulation (ERRS). These initiatives reflect Mexico's commitment to address shared regional coordination challenges, such as strengthening access to public health and sanitary response capacity.

Mexico's motivation behind these initiatives is the firm belief that the State plays a fundamental role both in ensuring universal access to health

and in the training of productive and technological capacities in the pharmaceutical industry, in partnership with the private sector. Furthermore, it is a task in which international organizations perform an extremely important role, as set out below.

Sanitary Regulation and PAHO

This is one of the most significant areas PAHO oversees, particularly in recent years due in part to Mexico's support for *sanitary regulation*, understood as verification that health products and services meet safety and quality standards. In this regard, PAHO works together with national regulatory systems, provides technical support for Member States in the drafting of policies, plans and strategies to ensure universal access to medicines, vaccines, and other health technologies. In addition, it contributes to capacity-building in governance and regulation and facilitating regional access to vaccines and medicines through initiatives such as acquisition mechanisms, collaborative networks, and regional platforms.¹

Similarly, one of the specific actions carried out by PAHO in terms of sanitary regulation is the coordination and support for the evaluation of the national regulatory authorities (NRAS) of its Member States, classifying the development of the system and laying the foundations for an institutional plan to guide improvements. The outcome includes the recognition of eight of the NRAS as regional reference national regulatory authorities (NRAR), indicating their importance in ensuring the safe and effective use of medicines and health technologies. In 2019, PAHO recognized the Federal Commission for Protection against Sanitary Risks (COFEPRIS) as an NRAR.

In addition, PAHO coordinates various regional and subregional regulatory mechanisms, including the Pan American Network for Drug Regulatory Harmonization (PANDRH). The objective of this network is to support pharmaceutical regulatory harmonization processes in the Americas, working

¹ PAHO, "Regulación de medicamentos y otras tecnologías sanitarias," at <https://www.paho.org/es/temas/regulacion-medicamentos-otras-tecnologias-sanitarias> (date of access: July 20, 2024).

on the basis of social realities, recognition of pre-existing asymmetries, and national and subregional sanitary policies.²

The principal objectives include the strengthening of the national regulatory systems through cooperation and exchange, developing proposals for health technologies, strengthening and using regulatory practices, as well as encouraging NRAs to develop and achieve common effective regulatory functions.³

In a context where each country has its own laws and procedures, where there are different needs and priorities, it could be seen as a complicated matter to speak of a joint, ordered, effective and large-scale health care response. However, the PANDRH has been characterized by its project implementation priorities, which consider the diversity of needs and seeking to establish joint results that benefit the majority of the population.

Although differences in regulations, institutional capacities and social realities make complete harmonization of pharmaceutical regulations difficult, our countries must aspire to convergence as a preliminary step to harmonization, which is essential to facilitate the exchange of medicines and medical supplies, as well as to promote production chains, in such a way as to promote production and trade in the industry and strengthen access to health.

The Pan American Conference for Drug Regulatory Harmonization

The PANDRH includes a structure that makes it possible to carry out the necessary objectives and actions in a more orderly manner, which is made up of the steering committee, the secretariat, the technical structures for the projects of the defined strategic areas, and the Conference of the Pan American Network on Drug Regulatory Harmonization (CPANDRH).

² PAHO, "The Pan American Network for Drug Regulatory Harmonization (PANDRH)," at <https://www.paho.org/en/pan-american-network-drug-regulatory-harmonization-pandrh> (date of access: July 20, 2024).

³ PANDRH, "Statutes," July 2009, p. 1, at <https://www.paho.org/en/documents/statutes-pan-american-network-drug-regulatory-harmonization> (date of access: July 20, 2024).

Specifically, the CPANDRH acts as a discussion forum for areas of common interest in the area of health regulation,⁴ with the participation of stakeholders involved in the different thematic areas. It is understood as a space to debate and bring together different positions and allows the exchange of knowledge that could be implemented in the region to harmonize processes and regulations and generate regional benefits.

Its objective is to promote cooperation and regional regulatory integration, to develop common proposals and to guide processes towards equitable access to effective, safe and quality pharmaceutical products.⁵

The CPANDRH has become a dissemination mechanism for recommendations relating to pharmaceutical harmonization of a range of global initiatives, such as the International Conference of Drug Regulatory Authorities (ICDRA) and the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH), of which PANDRH is a member.⁶

From August 21-23, 2024, the XI Conference of the Pan American Network on Drug Regulatory Harmonization was held in Mexico City, the first since covid-19. At this version of CPANDRH, Mexico took the position that, while the dialogue at the Conference is above all technical in nature, it is indispensable that it includes high-level political support, as it is essential to generate a regional political commitment and well-structured diplomatic collaboration to ensure that the cooperation ties bear fruit. In this regard, foreign ministers were invited to participate in order to harmonize the technical perspective with a foreign policy vision.

The intention of Mexico is to bring about improved coordination between the technical activities of the network and the policy decisions, thereby generating greater trust between countries; to translate decisions into recommendations for the different specialized spaces and mechanisms

⁴ *Ibid.*, p. 3.

⁵ Alejandro Svarch and Nemer Naime, "Red PARF, la armonía de los medicamentos," *La Jornada*, April 5, 2024, at <https://www.jornada.com.mx/2024/04/05/opinion/015a2pol> (date of consultation: July 20, 2024).

⁶ PAHO, "Red Panamericana..." section "Pan America Conferences for Drugs Regulatory Harmonization."

in the region, particularly in the area of regional cooperation, focused on reducing the differences in each country's regulatory institutional capacities; and to strengthen the rapprochement between governments and representatives of the regional pharmaceutical industry.

Diplomacy has a crucial role in establishing an equilibrium between political, commercial and regulatory interests. This balance is needed to ensure that the decisions taken by countries on harmonization and self-sufficiency in the field of health are viable from a political, economic and technical point of view and to ensure they benefit public health. The inclusion of these aspects will permit effective decision making focused on international cooperation.

Similarly, the presence of the productive sector at the Conference will be fundamental, since it provides the possibility of presenting the highest level of work in pharmaceutical research and innovation being undertaken. In addition, the collaboration between the productive sector and regulatory agencies will contribute to ensuring accessibility, quality and security of the medicines, and will optimize the production changes, significantly benefitting the population. A close collaboration between the actors promotes transparency and trust both in health products and the regulatory process.

In this way, the XI CPANDRH was an opportunity to bring together and coordinate the different sectors: health, economic, political, industrial and financial. It was also an opportunity for Mexico, as a regional leader in health matters, to consolidate the paths to achieve the objectives it has set for the benefit of the hemisphere.

Mexico and regional leadership in health matters

On the outbreak of the covid-19 pandemic in early 2020, the gaps in access to health services outside of the cities and disparities between our countries became clear. These were further exacerbated by the existing differences in regulatory systems. In turn, the health emergency put the issue of self-sufficiency in medicines and medical equipment on the agenda of all countries. The case of Latin America and the Caribbean was no exception.

Some regions faced greater challenges in procuring medical resources and effective containment measures, leading to the urgent need for regional coordination and cooperation to respond fairly and efficiently to the impacts of the pandemic. By the end of August 2021, Latin America and the Caribbean had recorded 32% of deaths, despite representing only 8.4% of global population.

In light of this situation, the need to reinforce regional collaboration and solidarity became clear, in order to ensure productive regulatory harmonization, with the aim of bringing about broader and better access to medicines and health services in general. In this way, Mexico became one of the leading countries in promoting initiatives for these needs both in the region and around the world.

Mexico's Pro Tempore Presidency of the Community of Latin America and Caribbean States (CELAC)

Just months after the pandemic was declared, the CELAC had already taken actions aimed at establishing a regional front to fight covid-19. The leadership of Mexico as President Pro Tempore (PPT) of the mechanism was primordial not only to underpinning and preparing an immediate response strategy for the pandemic, also to build health capacities in Latin America and the Caribbean. Even after relinquishing the PPT, Mexico has continued to drive forward this agenda with initiatives such as establishing a regional drugs agency and a regional sanitary regulation school.

The actions of Mexico in the framework of this Community make clear the significance of political will in developing regional plans that make it possible to confront health (and other) problems with a collective, future-oriented response.

On January 30, 2020, just 22 days after Mexico took over the PPT, the epidemic caused by covid-19 was declared an international emergency by WHO. In response to this situation, Mexico called for the first meetings of CELAC specialists to take place to monitor coronavirus. These served not only to update information on the new SARS-CoV-2 coronavirus, also to adopt a common front with a network of regional specialists. In the first place,

this network enabled a communications campaign and shared experience in the prevention of emerging outbreaks and, in the medium term, the creation of the CELAC's Network of Experts on Infectious Agents and Emergent and Reemergent Diseases.

As a follow-up to this work, in March 2020 Mexico convened the Virtual Ministerial Meeting on Health Issues for Response and Monitoring of the covid-19 Pandemic in Latin America and the Caribbean, which was attended by foreign ministers, ministers and representatives of the health sector from CELAC member countries. The event also included the collaboration of regional organizations such as PAHO, ECLAC, the Ibero-American General Secretariat (SEGIB), the Caribbean Community (CARICOM) and the Latin American and Caribbean Economic System (SELA). The participants reaffirmed the region's commitment to epidemiological surveillance of the SARS-CoV-2 virus and the ongoing exchange of experiences and best practices for situations of relevance to health.

One of the most important commitments resulting from this meeting was the request made by Mexico to ECLAC—on behalf of CELAC—to develop a covid-19 observatory in the region, in order to provide support for the follow-up and monitoring of the progress of the coronavirus. Cooperation with ECLAC was key to building projects under Mexico's leadership in CELAC, including the Plan for Self-sufficiency in Health Matters.

Plan for Self-sufficiency in Health Matters for Latin America and the Caribbean (PAS)

The PAS is a programmatic roadmap developed by ECLAC to strengthen the production and distribution of medicines, especially vaccines, in Latin American and Caribbean countries, with the aim of reducing the region's external dependence, as the recent pandemic had shown. The PAS was presented by the then Executive Secretary of ECLAC and later Foreign Minister of Mexico, Alicia Bárcena, during the Sixth Summit of Heads of State and Government of CELAC held in Mexico on September 18, 2021. It should be noted that the PAS was approved in this framework by the 33 countries that make up the regional mechanism.

During the presentation of the Plan, emphasis was placed on the fact that the pandemic laid bare the limitations of our region's health systems

and supply of medicines. As of September 2021, Latin America and the Caribbean had been unable to vaccinate 80% of its population. Hence the importance and urgency of greater regional coordination for health self-sufficiency.

The process for the development of the Plan included the creation of a vaccination observatory, which carried out an exhaustive monitoring of acquisitions, inoculation and creation of scenarios for fair access to immunization. In addition, a permanent group of 20 experts from different countries in the region was created. Analysis of the pharmaceutical industry was undertaken, and an inventory and diagnosis of the regional health capacities made, emphasizing the institutional capacities for design and implementation of policies.

In this context, seven lines of action were defined and prioritized: 1) strengthen the joint international purchasing mechanisms for vaccines and essential drugs; 2) use public drug purchasing mechanisms for the development of regional markets; 3) create consortiums for the development and production of vaccines; 4) implement a regional clinical trials platform; 5) take advantage of regulatory flexibilities to access intellectual property; 6) strengthen regulatory convergence and recognition mechanisms; and 7) strengthen primary health systems for universal access to vaccines and fair distribution. In the short term, PAS identifies immediate actions to be taken in three areas: coordination between national regulatory bodies, creation of regional purchasing mechanisms to achieve universal access to vaccines and the implementation of a regional clinical trials platform.

To implement this Plan, Mexico has continued to drive forward regulatory convergence through CELAC, heading up projects such as the formation of a sanitary agency for Latin America and the Caribbean.

Latin American and Caribbean Medicines and Medical Devices Regulatory Agency (AMLAC) and the Regional School for Sanitary Regulation (ERRS)

During the Seventh Summit of Heads of State and Government of CELAC (Buenos Aires, January 24, 2023), Mexico put forward a proposal to the Member States to join forces to create a Latin American sanitary agency

to help guarantee access to medicines and vaccines. Through this agency, a drug authorized in one country could be recognized throughout the region by means of a standardized procedure. This simple function would have been highly useful and opportune during the covid-19 pandemic, making it a very important tool.

Promoted by the COFEPRIS, together with the Ministry for Foreign Affairs, the first steps towards establishing this agency were set out: 1) achieve regulatory convergence and mutual recognition of sanitary authorizations, in order to ensure effective access to health supplies; 2) incentivize and facilitate research and development for innovative projects, ensuring regulatory certainty throughout the region; 3) support local production and the integration of regional supply chains and health products; and 4) explore public health purchasing mechanisms.⁷

Mexico, Colombia and Cuba, through their national regulatory agencies and respective foreign ministries, embarked on a series of dialogues and explored the foundations required to begin this coordinated work of regulatory convergence. On April 26, 2023, the national regulatory agencies of regional reference of Colombia, Cuba and Mexico met in Acapulco, where the Acapulco Declaration was adopted.

This Declaration formalized the negotiations for the creation of the Latin American drug agency. The agreements set out therein include the formation of working groups to prepare the AMLAC proposal; inviting the regulatory agencies of Argentina, Brazil and Chile as national regulatory agencies of reference (Level IV regulatory authorities certified by PAHO/WHO), and presenting the results of the upcoming work to the other CELAC members.

On June 15 and 16, at the Bogotá Summit, the six agencies of reference in the region agreed to work together to create the Regional School of Sanitary Regulation to support scientific and technical capacity-building for the regulatory health agencies; set up working groups to identify priorities for building regulatory trust in the region; and to share the reflections

⁷ COFEPRIS, “México propone constitución de Agencia Latinoamericana de Medicamentos como vía para la autosuficiencia sanitaria,” joint communiqué, January 24, 2023, at <https://www.gob.mx/cofepris/articulos/mexico-propone-constitucion-de-agencia-latinoamericana-de-medicamentos-como-via-para-la-autosuficiencia-sanitaria-324490> (date of access: July 20, 2024).

of the Summit at the meeting of national regulatory authorities of regional reference, to be held in Washington, D.C. in July 2023.⁸

During the Meeting of the National Regulatory Authorities of Regional Reference hosted by PAHO, where representatives of regulatory agencies from Argentina, Brazil, Canada, Chile, Colombia, Cuba and the United States participate, Mexico presented the Regional School for Health Regulation (ERRS) through COFEPRIS. In addition to training professionals specializing in the field, ERRS is designed as a space to promote regulatory convergence and a path for dialogue and ongoing preparation for the evaluation of national regulatory systems for medical products.⁹ In this same setting, the European Union, PAHO and COFEPRIS announced their intention to sign agreement for the creation of the ERRS.

The signing of the Declaration Establishing the Regional School for Health Regulation was held on August 25, 2023, at the headquarters of the Mexican Foreign Ministry. The Declaration includes a commitment by the European Union to contribute EUR 1.5 million—to be administered by PAHO—which will be used to boost the drugs and vaccines system and for the creation of the ERRS.

The ERRS has been hosted by the University of Health in Mexico City and began to deliver courses in the first semester of 2024. This is the first step towards overcoming the lack of professional training for technical sanitary personnel, impacting on the entire health system.

Conclusion

Mexico's role in supporting health self-sufficiency and drug regulation in Latin America and the Caribbean is a testament to the country's commitment to public health and regional cooperation. Through key initiatives

⁸ COFEPRIS, "Seis autoridades sanitarias de Latinoamérica asisten al Encuentro de Bogotá; el objetivo, la convergencia regulatoria," press release 63/2023, June 20, 2023, at <https://www.gob.mx/cofepris/articulos/seis-autoridades-sanitarias-de-latinoamerica-asisten-al-encuentro-de-bogota-el-objetivo-la-convergencia-regulatoria> (date of access: July 20, 2024).

⁹ COFEPRIS, "COFEPRIS presenta en OPS proyecto de Escuela Regional de Regulación Sanitaria," press release 77/2023, July 13, 2023, at <https://www.gob.mx/cofepris/articulos/cofepris-presenta-en-ops-proyecto-de-escuela-regional-de-regulacion-sanitaria> (date of access: July 20, 2024).

such as AMLAC, ERRS and PAS, Mexico has demonstrated a comprehensive and proactive vision to address the region's vulnerabilities and challenges.

Throughout its history, Mexico has shown its commitment to international bodies and the region to boost the cooperation mechanisms that guarantee quality in public health. The various efforts it has taken underscore its readiness to carry out joint actions to strengthen the region. The emergency arising from covid-19 reinforced Mexico's commitment to promote joint regional actions.

Mexican leadership, apparent in its work during the CELAC PPT and its collaboration with international bodies and mechanisms such as PAHO and the PANDRH, has been crucial to driving regulatory harmonization, strengthening emergency response capacity and ensuring more equitable access to medicines and sanitary technologies. Mexico's decisive response to the covid-19 pandemic and its continued drive toward regulatory convergence underscores its role as a central player in building a more robust and resilient regional health infrastructure.

Nevertheless, major challenges remain in our region and the covid-19 pandemic made clear that we must continue working to strengthen our health systems, access to medicines, vaccines and medical supplies, drug production and distribution capacities at a regional level, among other aspects that we can only make progress on by working in a coordinated manner. For this reason, insofar as the region continues to face emerging sanitary challenges, the model and initiative of Mexico offer a valuable guide to cooperation and strengthening of health systems. Sustained commitment to regional collaboration and innovation in sanitary regulation will be essential to ensuring a more secure and fairer future for all the nations in the region. Mexico's leadership and vision remains at the forefront of these efforts.