STRATEGİC ELEMENTS FOR BUİLDİNG HEALTH DİPLOMACY FROM THE SUPERİNTENDENCY OF HEALTH REGULATİON

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Discussion

In global health, diplomacy has established itself as a strategic tool for addressing transnational public health challenges by aligning its interests with foreign policies of Member States. This form of diplomacy facilitates international cooperation, regulatory harmonization, and equitable access to health technologies, particularly in crisis contexts. In Latin America, its evolution has been defined by the COVID-19 pandemic and the strengthening of technical mandates of National Regulatory Authorities (NRAs), whose Evidence-Based actions have gained significant prominence within global health governance.

In this context, the foreign policy of President Nayib Bukele's administration has adopted a pragmatic approach aimed at defending national interests, institutional sovereignty, and the international projection of technical capabilities. During the pandemic, the implementation of measures such as the construction of Hospital El Salvador, the national vaccination strategy, and the participation in multilateral mechanisms like the COVID-19 Vaccines Global Access (COVAX) Facility, demonstrated the State's capacity to integrate health actions with foreign policy instruments, thereby, strengthening its regional positioning.

Keywords: health diplomacy, sanitary regulation, intersectoral governance, regulatory convergence, international cooperation

The expertise gained during the health emergency underscored the need for a more robust and specialized regulatory body. This led to the establishment of the Superintendency of Health Regulation (SRS) in November 2023, which commenced operations in August 2024. Since its inception, this institution has centralized regulatory competencies that were previously fragmented and has assumed the oversight of health products under international standards, positioning itself as a cornerstone of El Salvador's health diplomacy.

Within this framework, the objective of the present research is to identify and analyze the strategic elements necessary for the construction of an institutionalized health diplomacy led by the Salvadoran SRS. This initiative seeks to bolster its role as the national technical authority, and to enhance its alignment with foreign policy and international health commitments.

a)Regulatory framework and normative backing

The legal framework underpinning the operations of the SRS is primarily established within the Medicines Law and the Superintendency of Health Regulation. These statutes define the essential competencies regarding the regulation, surveillance, and control of products subject to sanitary oversight. This regulatory framework reflects the commitment of the Salvadoran State to ensuring the quality, safety, innocuity, and efficacy of products with public health implications, while simultaneously strengthening regulatory sovereignty, and the protection of the right to health.

Nevertheless, when analyzing these provisions from an institutional and diplomatic perspective, it is observed that none of them explicitly confer upon the SRS the function of an international technical entity in matters of sanitary regulation. This restricts the institution's projection as a technical-diplomatic actor before multilateral forums, regulatory networks, and specialized agencies. Consequently, it is pertinent to vest the SRS with an express mandate recognizing it as the authority empowered to represent the Salvadoran State in international spaces for cooperation and regulatory convergence.

This proposal finds its foundation in the theory of "Pharmaceutical Law," understood as a branch of Public Law that regulates activities related to medicines and health products, ensuring their proper manufacture, distribution, and use, in accordance with public interest. According to Faus and Vida (2017), Pharmaceutical Law confers a distinct legal status upon regulatory authorities, predicated on technical independence, and the responsibility to protect collective health against risks arising from pharmaceutical activities.

The strengthening of the regulatory framework would also enable the overcoming of administrative constraints that currently restrict the SRS's participation in international training programs. At present, the national focal point for scholarship applications and cooperation programs is the Salvadoran Agency for International Cooperation (ESCO by its acronym in Spanish). This arrangement may constitute an administrative bottleneck by subjecting cooperation processes to screening criteria external to the technical purview of the SRS. Consequently, it is recommended that the Superintendency be granted the autonomy to directly manage the training of its specialized personnel, thereby facilitating its participation in capacity-building mechanisms (See Annex 1).

This model of technical and managerial autonomy aligns with international trends that promote the functional, financial, and legal autonomy of regulatory agencies, as a prerequisite for consolidating their institutional credibility and efficacy (PAHO, 2020; Kickbusch & Liu, 2022). The Pan American Health Organization (PAHO) has determined that those regulatory authorities with recognized autonomy and legal backing, are fundamental actors in global health governance, as they ensure technical continuity beyond political cycles, and facilitate the participation of nations in international decision-making processes.

In line with this approach, The Lancet (Kickbusch & Liu, 2022) indicates that health diplomacy constitutes a structural component of global governance, and that its institutionalization within state architecture—transcending individual leadership—is essential for maintaining coherent and sustainable national positions within multilateral forums.

Recent studies in Globalization and Health (2025) reaffirm this premise, demonstrating that the performance of health diplomacy improves when States establish explicit mandates, permanent structures, and organizational leadership. Within the region, experiences such as Colombia's Health Diplomacy Strategy or the COVID-19 Technology Access Pool (C-TAP) championed by Costa Rica, evidence how political and normative backing can translate into concrete diplomatic actions oriented toward cooperation and sanitary innovation (Minagricultura, 2018; WHO, 2021).

Furthermore, the Inter-American Development Bank (IDB) has underscored that new health diplomacy demands regulatory harmonization, coordinated international negotiation, and institutional leadership with a legal foundation (Granados & Villota, 2020).

In synthesis, strengthening the regulatory framework of the SRS and, complementarily, institutionalizing health diplomacy within foreign policy instruments, are interdependent and mutually reinforcing processes. The former provides the legal and technical basis for action, while the latter ensures its political and intersectoral backing.

b)Intersectoral governance

Sanitary governance needs an openness toward non-state actors—including academia, the private sector, civil society, and industry—with the dual purpose of ensuring legitimacy and sustainability. From the perspective of policy framing theory, health enters the foreign policy agenda through lenses of security, development, global public goods, trade, and human rights. Within these frameworks, public deliberation and co-produced evidence (involving social actors) bolster the quality of decision-making and institutional buy-in (Labonté & Gagnon, 2010).

Recent practice validates this approach: the C-TAP initiative, proposed by Costa Rica and adopted by WHO, demonstrated that a multi-stakeholder design—involving universities, developers, and manufacturers—enables the translation of health objectives into intellectual property arrangements and technology transfer, with global impact, provided there is clear state coordination (WHO, 2021). Furthermore, Latin American health networks and leadership training platforms promoted by PAHO, have functioned as intermediary spaces that integrate scientific, regulatory, and foreign policy expertise, into the development of national positions (PAHO, 2019, 2023).

In El Salvador, Decree No. 302, which encompasses the National Integrated Health System Law (2019), establishes that the system is composed of public and private institutions directly or indirectly related

to health, under the stewardship of the Ministry of Health (MINSAL, by its acronym in Spanish). This legal framework recognizes the necessity for coordination and complementarity among the various actors within the system, configuring an institutional architecture that creates an avenue for the exercise of health diplomacy. Within this context, the SRS, by centralizing sanitary regulatory competencies and possessing technical autonomy, holds an ideal foundation to assume a coordinating role within the National Integrated Health System (SNIS, by its acronym in Spanish), serving as the technical focal point for health diplomacy and international cooperation.

At an operational level, the SRS could promote, in coordination with MINSAL, a Technical Secretariat for an Inter-Ministerial Committee on Health Diplomacy (CIDS, by its acronym in Spanish). This committee, in alignment with PAHO recommendations on intersectoral coordination, could permanently integrate the Ministries of Health, Foreign Affairs, Economy, and Agriculture, with the participation of Finance or Budgeting when financial commitments are addressed (See Table 1).

Table 1. Thematic roundtables suggested by CIDS

Thematic roundtable	Main actors	Purpose	Expected results
1. Regulation and Healthcare Convergence	SRS, MINSAL, Ministry of Foreign Affairs and the Pharmaceutical Industry	Harmonizing technical standards, promoting mutual recognition agreements (MRAs), and participating in regional regulatory networks	Harmonized guidelines, inspection protocols, and participation in the Central American Network of Regulatory Authorities for Medicines and other Health Technologies (REDCAM, by its acronym is Spanish), CODEX, WHO
2. Innovation, intellectual property and access	SRS, Ministry of Foreign Affairs, Ministry of Economy, universities, developers y manufacturers	Engaging in dialogue on technology transfer models, voluntary licensing, and biotechnology cooperation	Open innovation strategies and participation in initiatives such as C-TAP or PANDRH
3. Training and international technical cooperation	SRS, MINSAL, PAHO, national and international universities	Strengthening capacities through fellowships, rotations, certifications, and health diplomacy programs	Joint training programs and the establishment of a School of Regulation and Health Diplomacy
4. Communication, civil society and transparency	SRS, Ministry of Foreign Affairs, civil organizations, media and professional networks	Promoting public dialogue, accountability, and social participation in regulatory decision-making	Transparency portal, repository of minutes, and public consultations
5. Health security and emergency response	SRS, MINSAL, Civil Protection and international organizations	Coordinating positions and protocols for health emergencies and International Health Regulations (IHR) notifications	National response plan and improvement of IHR indicators

Source: self-elaboration

Furthermore, intersectoral governance must be grounded in accountability, evaluation, and institutional learning. PAHO reports on the IHR recommend measuring capacities and outcomes through public dashboards and periodic indicators (PAHO, 2023). In this regard, El Salvador could adopt a scorecard including indicators for:

- Process: number of CIDS sessions, attendance by portfolio, average lead time for country positions, and number of public consultations and participants.
- Output: approved country positions, harmonized guidelines or procedures, mutual recognition agreements, and leadership roles assumed in regional networks (REDCAM, CODEX, WHO).
- Outcome: reduction in regulatory lead times for prioritized procedures, increased pharmacovigilance reporting, compliance with IHR notifications, and effective utilization of technical and financial cooperation.

Table 2. Proposed Indicators for CIDS Scorecard

Dimension	Indicator	Unit of measure	Source / Responsible	Periodicity
Process	Number of regular CIDS sessions held	N. º of meetings	Technical Secretariat SRS + MINSAL	Quarterly
	Attendance rate of member ministries	% of participation	Technical Secretariat SRS + MINSAL	Quarterly
	Number of public consultations and registered stakeholders	N. º of consultations / people	SRS + MINSAL	Semi-annual
	Average turnaround time for national position papers	Business days	Ministry of Foreign Affairs / SRS / MINSAL	Semi-annual
Product	National positions adopted in international forums	N. º of positions	Ministry of Foreign Affairs	Annual
	Regionally harmonized procedures and guidelines	N. º of documents	SRS / MINSAL	Annual
	Signed Mutual Recognition Agreements (MRAs)	N. º of agreements	Ministry of Foreign Affairs / SRS / MINSAL	Annual
	Engagement in regulatory networks (REDCAM, CODEX, WHO)	N. º of events / leaderships	SRS / MINSAL	Annual

Dimension	Indicator	Unit of measure	Source / Responsible	Periodicity
Result / Impact	Reduction in average turnaround times for prioritized regulatory filings	% Reduction	SRS Intendancies	Annual
	Increase in pharmacovigilance and post-market surveillance reporting	% Increase	SRS / MINSAL	Annual
	Compliance with IHR notification requirements	% Compliance	MINSAL / SRS	Annual
	Leveraging international technical and financial cooperation	N. º of projects / amount (USD)	SRS / ESCO	Annual

Source: Self elaboration based on (PAHO, 2023), (WHO, 2024), (Think Global Health, 2025).

Furthermore, the literature emphasizes that tacit knowledge transfer within communities of practice requires learning metrics (e.g., international rotations, certifications, co-authorships, and network engagement), as these factors determine the sustainability of the diplomatic-technical ecosystem (Rosenbaum et al., 2025). Regarding transparency, it is recommended to establish a public institutional repository containing summarized minutes, national position papers, evidence matrices, and forum schedules, restricting information only when justified by security concerns or commercial confidentiality (Think Global Health, 2025).

Additionally, academic cooperation alliances reinforce this intersectoral architecture. The SRS maintains institutional ties with the Faculty of Medicine at University of El Salvador (UES, by its acronym in Spanish), the Faculty of Chemistry and Pharmacy at Nueva San Salvador University (UNSSA, by its acronym in Spanish), the Supreme Court of Justice (CSJ, by its acronym in Spanish), and the National Council of the Judiciary (CNJ, by its acronym in Spanish). The latter has integrated Pharmaceutical Law into its judicial training programs, providing legal practitioners with specialized training on crimes related to the falsification, and illicit trade of medical products.

c)Engagement in Multilateral Networks and Forums

Contemporary health diplomacy is rooted in regulatory interdependence and multilateral cooperation. According to Kickbusch, Silberschmidt, and Buss (2007), active state participation in international health forums constitutes a mechanism of technical power, through which national agencies expand their sphere of influence via knowledge exchange, and normative convergence. Under this logic, El Salvador's presence in multilateral spaces not only strengthens the country's legitimacy with strategic partners, but also bolsters confidence in its regulatory framework.

The SRS possesses the necessary legal and technical competencies to assume this role. Its engagement in networks such as the Network of Regulatory Authorities for Medicines and other Health Technologies (REDCAM), the Codex Alimentarius, the Programme for International Regulatory Cooperation (PRC/WHO), the Coalition for Epidemic Preparedness Innovations (CEPI), and the Uppsala Monitoring Centre (UMC), would enable access to high-level scientific and regulatory information, sharing of expertise in pharmacovigilance and post-market surveillance, and promotion of regional harmonization initiatives (PAHO, 2025; WHO, 2024).

According to governance network theory (Rhodes, 1997), multilateral networks operate as collective learning systems where sustained peer-to-peer cooperation fosters institutional innovation. Regional evidence suggests that agencies assuming leadership roles in technical forums achieve greater visibility, capacity transfer, and preferential access to international cooperation.

d)Regulatory innovation and convergence

Regulatory innovation constitutes a fundamental pillar for the strengthening of health diplomacy, enabling States to adapt their legal frameworks to scientific and technological advancements without compromising public safety. According to Abbott and Snidal (2009), regulatory convergence emerges as a response to increasing global interdependence, seeking to align national standards through the principle of functional equivalence, whereby countries mutually recognize standards that guarantee equivalent health outcomes. This approach has been adopted by organizations such as the International Council for Harmonisation (ICH) and the Pharmaceutical Inspection Co-operation Scheme (PIC/S, 2022), which promote technical harmonization in medicines, Good Manufacturing Practices (GMP), and clinical trials (ICH, 2023).

For El Salvador, the SRS represents the ideal entity to lead this process. Its technical autonomy and comprehensive skills position it to advance toward reliance mechanisms and mutual recognition, which allow the leveraging of decisions made by stringent regulatory authorities (SRAs), such as the European Medicines Agency (EMA) or the U.S. Food and Drug Administration (FDA), to shorten evaluation timelines without compromising rigorous criteria. WHO recognizes these practices as essential for optimizing resources, enhancing transparency, and facilitating equitable access to health products (WHO, 2023).

Furthermore, the implementation of a regulatory sandbox-or a controlled experimentation environment-would allow the SRS to evaluate emerging technologies under supervision, such as artificial intelligence applied to pharmacovigilance, biotechnological products, and smart medical devices. This tool, already utilized by the United Kingdom's Medicines and Healthcare Products Regulatory Agency (MHRA), and Health Canada, fosters responsible innovation by combining regulatory flexibility with scientific oversight (Organization for Economic Co-operation and Development [OECD], 2022).

e) Sustainable Financing

Financial sustainability is a structural component of any health diplomacy policy. According to PAHO (PAHO, 2020), global health strategies require not only political will, but also stable institutional financing mechanisms capable of sustaining cooperation, talent development, and international engagement. In this regard, the SRS must shift toward a mixed model that combines national budget allocation, international cooperation mobilization, and the management of self-generated projects within a global health framework.

The experiences of Chile and Colombia provide valuable references. Chile, through the Institute of Public Health (ISP, by its acronym in Spanish), allocates a permanent budget line for international cooperation, and maintains technical agreements with PAHO and EMA for regulatory capacity building (ISP Chile, 2023). On the other hand, the Brazilian Health Regulatory Agency (ANVISA, by its acronym in Portuguese), has diversified its funding sources through projects co-financed by the IDB and the World Bank, aimed at innovation and regulatory convergence. Both models demonstrate that investment in technical diplomacy strengthens State's capacity to participate actively in global health governance.

In El Salvador, the proposal entails establishing a specific budget allocation for health diplomacy, integrated into the SRS's institutional budget, asigned to cooperation activities, capacity building, and participation in international networks. Complementarily, the SRS could elaborate a

portfolio of strategic projects aligned with the Sustainable Development Goals (SDG 3 and 17), and the International Health Regulations (IHR), facilitating the acquisition of cooperation funds from PAHO, WHO, IDB, and the World Bank.

The present research constitutes an initial contribution to the study of health diplomacy from a Salvadoran perspective, centered in the institutional experience of the SRS. Its scope is academic and reflective in nature; it does not represent an official position by the SRS or the Salvadoran State, but rather, an analytical effort aimed at identifying the strategic elements that could underpin national health diplomacy.

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Annex 1: Elements for autonomy in capacity building

Constraints/ Challenges	Brief Description	Implication for Health Diplomacy
1. Strengthening Inter-institutional Coordination	Promoting formal coordination mechanisms among the SRS, the Ministry of Health (MINSAL), the Ministry of Foreign Affairs, and other entities related to health, trade, and cooperation	The absence of permanent mechanisms hinders the formulation of coherent national positions and limits the State's capacity to engage effectively in international forums
2. Limited Coverage and Operational Capacity	The SRS's territorial presence remains insufficient, particularly outside the metropolitan area, which restricts surveillance and coordination with local stakeholders	It reduces the ability to generate national evidence and maintain a robust technical representation in regional forums
3. Fragmented Information Management	Sanitary and regulatory information is dispersed across different units and lacks interoperability between institutions	It limits Evidence-Based decision-making and the ability to prepare real-time reports or technical positions
4. Training and Institutional Coordination in Health Diplomacy	SRS technical staff requires capacity building in health diplomacy, international negotiation, and cooperation management. The Ministry of Foreign Affairs and other state cooperation units could provide support through joint training and professional development programs	Expanding diplomatic training programs into the health sector and strengthening coordination between state institutions would allow for the consolidation of a critical mass of professionals with competencies in technical diplomacy

Source: self-elaboration