REGULATORY STRENGTHENING OF *IN VITRO* MEDICAL DEVICES IN IBERO-AMERICA: ADVANCES, CHALLENGES, AND PERSPECTIVES

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Discussion

In vitro diagnostic medical devices (IVD) have established themselves as essential tools for clinical decision-making and public health interventions. By allowing the detection, monitoring, and prevention of community-related diseases, their impact on public health depends directly on the strength and consistency of regulatory frameworks to guarantee quality, safety, performance, and availability. In a time characterized by the expansion of digital commerce and the globalization of healthcare markets, strengthening regulatory frameworks become important to ensure that IVD reaching the public meet adequate quality standards, safety, performance and clinical efficacy. In this context, the Superintendency of Health Regulation (SRS) recognizes the importance of moving progressively, in a coordinated and strategic way, towards a robust regulatory model harmonized with international best practices.

In Ibero-America, the regulatory systems have different regulatory levels, which result in substantial differences in risk classification, clinical evidence requirements, compliance evaluation processes, post-marketing surveillance, and mutual recognition or regulatory dependency mechanisms. Such diversity generates asymmetries in quality and access to IVD, as well as obstacles for the regional harmonization and convergence with international standards, such as those promoted by the International Medical Device Regulators Forum (IMDRF), World Health Organization (WHO), or Regulation (EU) 2017/746 of the European Parliament and the Council, dated April 5th, 2017, on *in vitro* diagnostic medical devices, and repealing Directive 98/79/EC and Commission Decision 2010/227/EU on the regulation of *in vitro* diagnostics medical devices (IVDR).

Keywords: *in vitro* diagnostic medical devices, regulatory strengthening, regulatory harmonization, post-market surveillance

Additionally, SARS-CoV-2 pandemics (COVID-19 causal virus) exposed structural weaknesses with the performance assessment, market surveillance and detection of counterfeit products or products with not enough evidence, especially in countries with limited institutional capacities. The accelerated technologic innovation and the e-commerce have intensified these challenges, increasing the need for quality, agile, risk-based regulatory systems.

In this context, countries like El Salvador face the challenge of enhancing regulatory structures, reducing requirement duplication, improving reactive surveillance, adopting international tools and guaranteeing IVD entering the market comply with acceptable standards of quality and performance. Without comprehensive strengthening, there is a risk of greater inequality in diagnostic essential technologies, poorly efficient regulatory processes, and limitations in responding to health emergencies or emergent epidemiological needs.

Therefore, it becomes necessary to comparatively analyze the reference regulations in the region, and identify those elements that allow designing strategies for progressive strengthening, which should be realistic and sustainable, aligned with national needs and international progress.

In the Ibero-American region, the regulatory strengthening process has been accompanied by a joint discussion, driven by multilateral technical forums and the European thrust derived from IVDR. Although the regulatory and operative reality of the countries is different, all these experiences provide valuable elements on surveillance mechanisms, conformity assessment, traceability, and regulatory transparency, that may target continuous improvement processes in countries with developing systems such as El Salvador (Lubbers et al., 2021).

The IVDR has been a paradigm shift in the regulatory approach to IVDs. Its emphasis in clinic evidence, risk management, enhanced documentary traceability, and the extended responsibility of economic agents represents an important evolution from the traditional models based exclusively on prior quality control. Various authors recognize the transition to stronger regulatory frameworks has required significant adjustments in regulatory capabilities, post-market surveillance structure, and assessment mechanisms (MDCG, 2022). While Europe remains in transition to full implementation, the IVRD components offer valuable benchmarks that can inspire gradual improvements adapted to national contexts.

The ability to diagnose rapidly and accurately is fundamental in any modern healthcare system. In Latin America, public health situations highlight the crucial role of IVDs, while simultaneously revealing the limitations derived from regulatory disparities across countries. Although some countries have established strong and specialized regulatory frameworks for IVDs, others are still ruled by general medical device regulations, or are in the process of developing their own specific guidelines.

Brazil is one of the countries with specific regulations for IVDs; according to the National Health Surveillance Agency (ANVISA), Collegiate Board Resolution RDC No. 36 (dated August 26, 2015) establishes risk classification criteria, control regimes (registration or notification depending on the device class), labeling requirements, and instructions for use, and evidence on safety, performance, and Good Manufacturing Practices (GMP) for higher-risk products is mandatory (Ministry of Health, 2015). This framework positions ANVISA as one of the most developed regional authorities regarding IVDs regulation.

On the other hand, the Secretariat of Health of Mexico, highlights that IVDs, through the Federal Commission for Protection against Sanitary Risks (COFEPRIS), are regulated under the Health Supplies Regulation and other official standards, such as: NOM-241-SSA1-2025 (Good Manufacturing Practices for Medical Devices) and NOM-137-SSA1-2008 (Labeling of Medical Devices), which establish classification requirements, registration and sanitary controls, while including simplification measures for low-risk products, and mechanisms for external conformity assessment.

Similarly, in Colombia, medical devices —including IVDs— are regulated under Decree 4725 / 2025 and its updates, applying risk classification and demanding sanitary registration, technical documentation, and performance validation, for controlled products. Its national regulatory authority, the National Institute for Drug and Food Surveillance (INVIMA), also participates in regional cooperation forums for regulatory harmonization (Ministry of Health and Social Protection, 2005).

Argentina, through its National Administration of Drugs, Foods, and Medical Technology (ANMAT), operates based on regulations such as Provision 2318/2002 (and its subsequent updates). These regulations require sanitary registration, quality testing, and post-market reactovigilance. These are key elements to guarantee the safety of IVDs, and have been aligned with international standards, such as those from the International Organization for Standardization (ISO), and WHO recommendations (ANMAT, 2002).

Other Latin American countries have incorporated more specific standards for these types of products, through their respective regulatory agencies. This includes the issuance of regulations, registration requirements, administrative procedures, and specific regulatory frameworks for medical devices, including IVDs.

In El Salvador, SRS has progressively strengthened its regulatory role in the field of medical devices, including IVDs, performing actions oriented to

sanitary authorization, inspections, market surveillance, techno-surveillance, and inter-institutional articulation. However, it is recognized that technological advances, the rise of ecommerce, the diversification of manufacturers and distributors, require an updated regulatory approach that integrates tools for more proactive risk-based monitoring. International experience shows that balance between regulatory control and easy access, is only sustainable when regulatory processes are supported by rigorous scientific assessments and robust post-market surveillance systems (European Commission, 2017).

One of the shared challenges in Ibero-America is strengthening post-market performance surveillance of IVDs. The COVID-19 pandemic highlighted the need for agile mechanisms to detect performance failures, counterfeiting, or the distribution of diagnostic tests without sufficient clinical evidence. Numerous regulatory authorities in the region have emphasized that techno vigilance, market control, and cross-border cooperation, have become indispensable pillars for protecting the population, particularly against rapid circulation of products of unknown origin, or lacking recognized certifications (PAHO, 2020). In this regard, regional technical dialogue has helped to identify strengthening strategies, ranging from targeted control campaigns to the exchange of health alerts, and technical criteria for IVD risk classification.

Regulatory harmonization constitutes a necessary cross-cutting axis to advance towards more efficient and reliable regulatory systems. The adoption of convergent guidelines helps reduce regulatory disparities between countries, promotes mutual recognition of assessments, and fosters greater transparency among authorities and stakeholders within the system. Cooperative experiences between European and Ibero-American regulatory agencies, indicate that technical exchange processes and continuous training of regulatory personnel have served as facilitating elements for sustainable regulatory evolution, particularly in areas such as conformity assessment, risk classification, and clinical performance analysis (FDA, 2022). For El Salvador, strengthening its participation in these areas can translate to greater capacity to anticipate emerging risks and adapt Evidence-Based regulatory tools.

After analyzing all regional regulatory efforts, three clear trends can be observed (Figure 1):

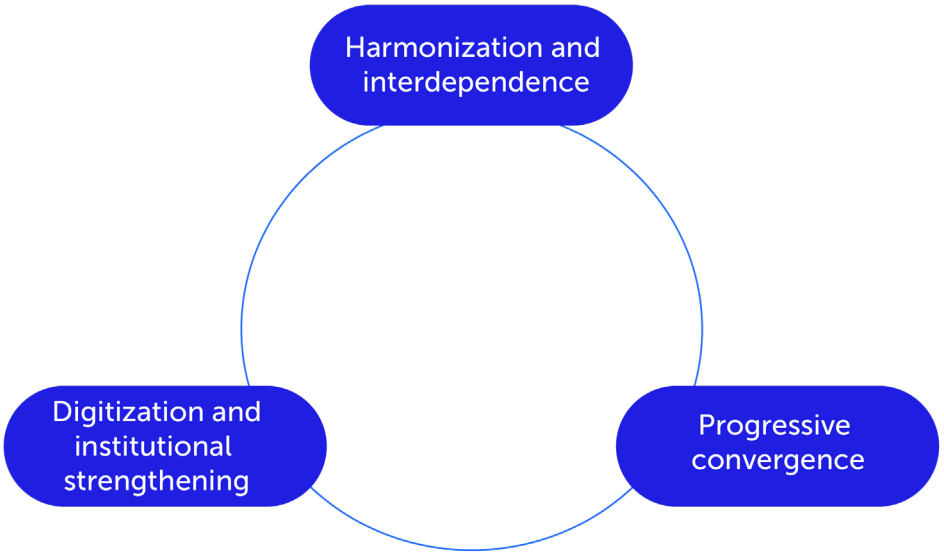
- Progress towards harmonization and interdependence. The region is working through forums and networks to share best practices, promote Essential Diagnostics Lists (EDLs), and leverage interdependence mechanisms—that is, benefiting from assessments conducted by reference authorities or the WHO, to avoid duplicating procedures and expedite access (PAHO, 2023).

- Digitalization and institutional strengthening. Many regulatory bodies have made progress in digitizing procedures and publishing technical guidelines, which improves predictability and transparency for manufacturers and importers.

- Progressive convergence towards risk and Evidence-Based regulatory frameworks. Countries in the region are modernizing their regulations to align with international standards (such as IMDRF, WHO, and the European IVDR), prioritizing:

- Risk-based device classification
- Clinical evidence and performance requirements
- Reinforcement of the obligations of economic operators

Figure 1. Regional trends in regulatory efforts



Source: self-elaboration

The role of the SRS, as the national regulatory authority, is oriented precisely toward this objective: ensuring health protection through the gradual strengthening of a comprehensive, modern regulatory system that is articulated with global advancements. This entails continuing to promote spaces for technical training, international collaborations, and internal processes that consolidate clear, uniform, and sustainable regulatory criteria over time. Recent experience in technical exchange forums, such as the push to strengthen the IVD regulatory framework in Ibero-America, constitutes an opportunity to enrich national policies, and contribute to a shared regional vision while respecting the institutional realities of each country.

The regulatory development of IVDs requires a strategic approach that combines regulation, surveillance, cooperation, and institutional strengthening. From a diplomatic perspective, yet mindful of challenges, it is possible to affirm that El Salvador is well-positioned to continue advancing toward a mature regulatory model, aligned with international standards and adapted to the country's needs. Strengthening the regulatory framework should not be perceived as a burden, but rather as a process that protects the population, drives responsible innovation, and promotes trust in the healthcare system.

There are challenges that must be taken into account, which include duplication of required evidence, increased time and costs for market access, and inequalities in test availability.

To mitigate these risks, various actions can be implemented, such as those mentioned below:

- Adopt formal mechanisms of mutual recognition and regulatory reliance (when the evidence comes from authorities or processes with verifiable standards, such as WHO prequalification) to accelerate the availability of essential IVDs without compromising safety (WHO, 2021).

- Promote post-market surveillance and technical training to concentrate regulatory resources on higher-risk products, while simultaneously simplifying processes for low-risk IVDs, which already possess solid evidence and international recognition.

According to the International Medical Device Regulators Forum (IMDRF, 2020), recent experience demonstrates that spaces for technical dialogue and exchange among health authorities from different countries, have become an essential component for regulatory strengthening regarding IVDs.

These meetings allow sharing lessons learned, comparing approaches, and building common solutions to challenges that transcend borders. Maintaining active participation in these forums not only favors technical updating, and harmonization of criteria, but also strengthens national and regional capacities to protect the population, and ensure access to high-quality diagnostic technologies.

The SRS reaffirms its commitment to advance along this path, promoting a collaborative and technically grounded approach. Through joint work with regional authorities, cooperation agencies, and healthcare sector stakeholders. This makes it possible to consolidate an integrated vision to strengthen El Salvador's regulatory system while simultaneously contributing to regional harmonization efforts for the benefit of public health.

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