Implementation of Reliance in Paraguay

Industry Perspective and Experience

Roberta Mele Mazza, Pharm.D.

Director of Quality and Regulatory Affairs

Roche Argentina, Uruguay, Bolivia, and Paraguay.

Member of the IACRC Executive Committee

ATCET-26

Email: roberta.mele_mazza@roche.com

LinkedIn: Roberta Mele Mazza

Paraguay's Regulatory Evolution: A Rapid Transformation

A Paradigm Shift

In recent years, DINAVISA has transitioned from basic oversight to an agile and iterative regulatory model, issuing more than 10 landmark regulations to modernize the sector.

Adopting Global Standards

Key updates, such as the first regulation on IVDs (*in vitro* diagnostic devices) (Res. 266/22) and the creation of the Reliance Manual (Res. 147/24), demonstrate a strong government commitment to aligning with PAHO/WHO and IMDRF frameworks.

The Industry as a Strategic Partner

Navigating this rapid evolution has required continuous adaptation, highlighting the need for a collaborative ecosystem where regulators and technology developers work in complete synergy.

Summary of the Transformation

A rapid evolution toward international alignment and collaborative synergy.

The First Milestone: Resolution 266/2022

Before Resolution 266/22

- IVDs and medical devices were regulated by the Central Laboratory.
- Market entry involved a simpler registration process with fewer requirements.
- Registration with the Central Laboratory was primarily for customs purposes

After Regulation 266/22

- DINAVISA is responsible for regulating IVDs and medical devices
- MERCOSUR guidelines apply to Paraguay's regulatory framework

Impact

Massive re-registration of products with expiration dates tied to the renewal of the company's license, 5 (five) years

The Big Leap in Efficiency: Resolution No. 44/2024

Resolution 44/24

Introduction of the Simplified Registration Procedure (PSR) to streamline the health registration of *in vitro* diagnostic (IVD) products.

Reference Regulatory Authorities

- PAHO/WHO Reference Regulatory Authorities.
- Members of the IMDRF (International Medical Device Regulators Forum).
- Authorities with bilateral agreements in force with DINAVISA.
- Countries listed in DINAVISA Resolution 148/2024 and its amendments (Medical Devices).

Direct impact: The PSR takes only **15 days** (*)

The fastest regulatory evaluation agency in the region.

Ref: https://dinavisa.gov.py/wp-content/uploads/2024/04/Resolucion-DINAVISA-44.24.pdf
(*) Pending full system implementation for IVDs.

Consolidating the Model: From Theoretical Framework to Day-to-Day Operations

Asymmetry in Digital Tools

Selection in the PSR system is currently limited to medical devices, which leaves an operational gap for IVDs.

Lack of Operational Traceability

Lack of metrics to distinguish between PSR and traditional evaluation pathways.

Resource constraints

The massive re-registration process (Res. 266/22) creates bottlenecks, diverting resources towards clearing the backlog.

Regulatory Gap (Post-Approval)

Uncertainty due to the lack of a structured framework for post-approval modifications under the reliance model.

Lack of a digital pharmacovigilance pathway

DINAVISA's platform lacks automated channels for seamless tecnovigilance/post-marketing reporting.

Driving Progress: Industry Evolution and Strategic Collaboration

Strengthening local industry associations

Local and regional associations are making progress in establishing specialized Working Groups on Regulatory Affairs to provide structured technical support and adopt international best practices.

Leveraging Manufacturers' Technical Expertise

The private sector is ready to implement agile channels for knowledge transfer, contributing the specialized technical and technological expertise that is exclusive to manufacturers.

Joint Strengthening of Technical Capabilities

The private sector and regulatory authorities are well-positioned to jointly design training programs aligned with international models (for example, the IMDRF Reliance Playbook) to promote the ongoing training of the institution's technical staff.

Institutionalizing public-private dialogue

The creation of predictable and proactive channels for technical discussion helps prevent operational gaps before new regulations are implemented in digital systems.

Conclusion

Paraguay is demonstrating a genuine paradigm shift. In contrast to the region's traditional, more static regulatory dynamics, DINAVISA has opted for a process of constant iteration and accelerated regulatory development. For a highly innovative sector like ours, a regulatory authority that evolves at this pace becomes a strategic ally.

The current challenge—and our proposal as industry—is to collaborate closely so that this regulatory agility is effectively translated into day-to-day operations, ensuring that safe innovation in medical technology positively impacts patients in record time.