IMDRF International Medical Device Regulators Forum

HSA Health Sciences Authority 25 YEARS AND BEYOND

30th IMDRF 2026

Day 2 IMDRF Stakeholder Forum | 15 September 2026

Regulatory update: DINAVISA

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Director

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DIRECCION NACIONAL DE VIGILANCIA SANITARIA PARAGUAY

National Directorate of Health Surveillance – DINAVISA

1997 Law 1119/97 creates the National Directorate of Health Surveillance (DNVS) dependent on the Ministry of Public Health and Social Welfare

2021 Law 6788 is enacted, establishing the competence, powers and organic structure of the "National Directorate of Health Surveillance "DINAVISA LAW"

AUTONOMY
Legislative, normative and regulatory independence

STRATEGY

AUTARCHY
Institutional administrative decentralization

From a Regulatory model to a Proactive supervisory model

16 REGIONAL HEALTH SURVEILLANCE DEPARTMENTS (DRVS)

DINAVISA has 16 Regional Departments of Health Surveillance throughout the country to ensure a decentralized, close and effective management.

1. Concepción
2. San Pedro Norte
3. San Pedro Sur
4. Cordillera
5. Guairá
6. Caaguazú
7. Caazapá
8. Itapúa
9. Misiones
10. Paraguarí
11. Central
12. Ñeembucú
13. Amambay
14. Canindeyú
15. Alto Paraná
16. Boquerón

Our regional presence allows us to be closer to the communities, strengthening sanitary control and contributing to the well-being of all Paraguayans.

Medical Device regulation - Paraguay

- ## Reliance mechanisms for pre-market authorizations:

2024: Resolución DINAVISA N°226/2024 “Por la cual se establecen los requisitos para obtener la autorización de comercialización de los Dispositivos Médicos, modificaciones post autorización y renovaciones de los mismos”.

Resolución DINAVISA N°44/2024 **“**Por la cual se establece el Proceso Simplificado de Registro Sanitario (PSR) de Productos para Diagnóstico de Uso *In Vitro* , previamente autorizados por Autoridades Reguladoras de Referencia para su comercialización.”

DINAVISA

- ## Medical Devices Intended for Compassionate Use:

2025: Resolución DINAVISA N°203/2025 “Por la cual se reglamenta la autorización de importación de medicamentos y dispositivos medicos que no cuenten con Registro Sanitarios emitidos por la DINAVISA, destinados al uso compasivo.”

Medical Device regulation - Paraguay

- **MERCOSUR Resolutions:**

2024: Resolución GMC MERCOSUR N°07/24 “Reglamento Técnico MERCOSUR Requisitos Esenciales de Seguridad y Desempeño de los Productos Médicos y Productos médicos para diagnóstico in vitro”

2025: Decreto N° 5176: Por la cual se incorpora al ordenamiento jurídico nacional la Resolución GMC MERCOSUR N°07/24 “Reglamento Técnico MERCOSUR Requisitos Esenciales de Seguridad y Desempeño de los Productos Médicos y Productos médicos para diagnóstico in vitro”

“Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices (IMDRF/GRRP WG/N 47 FINAL 2018”

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MERCOSUR

Medical Device regulation - Paraguay

- **MERCOSUR Scope: Under development “ADVANCED” stage**

✓ **Customized Medical Devices**

As reference: **IMDRF/PMD WG/N 49 FINAL 2018** Title Definitions for Personalized Medical Devices

IMDRF/PMD WG/N 74 FINAL 2023 Tittle Personalized Medical Devices Production Verification and Validation

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DINAVISA: Under development “intermediate” stage

✓ **Artificial Intelligence/Machine Learning-enabled (AI/ML) medical devices**

As reference: **IMDRF/AIML WG/N88 FINAL:2025** Good machine learning practice for medical device development: Guiding principles

DINAVISA

Participation: IMDRF Working Groups

Adverse Event Terminology

Harmonize terminology for reporting adverse events related to medical devices, and further harmonize adverse event reporting datasets to improve signal detection.

Foundational Documents

Seeking to establish a comprehensive set of IMDRF documents as a reference for members and stakeholders in developing their regulatory frameworks, while supporting continued global harmonisation

Good Regulatory Review Practices

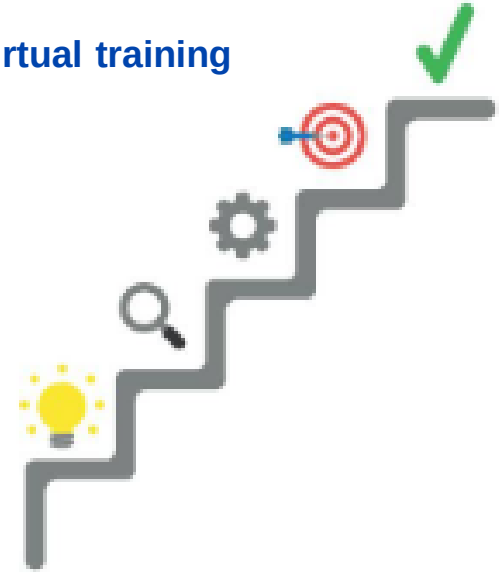
Develop good review practices for pre-market reviews and evaluations.

Benefits of participating as an IMDRF Affiliate Member:

- Regulatory Convergence
- Strengthening the regulatory system
- Facilitation of information exchange between regulatory authorities
- Access to high level training
- Participation in IMDRF working groups
- Regional Positioning
- Promotion of innovation and patient access to safe and effective devices

Next steps…

- Training on IMDRF technical documents on DINAVISA's new virtual training platform
- Development and implementation of new standards
- Strengthening post-marketing control
- Active participation in the IMDRF working groups



Thank You!