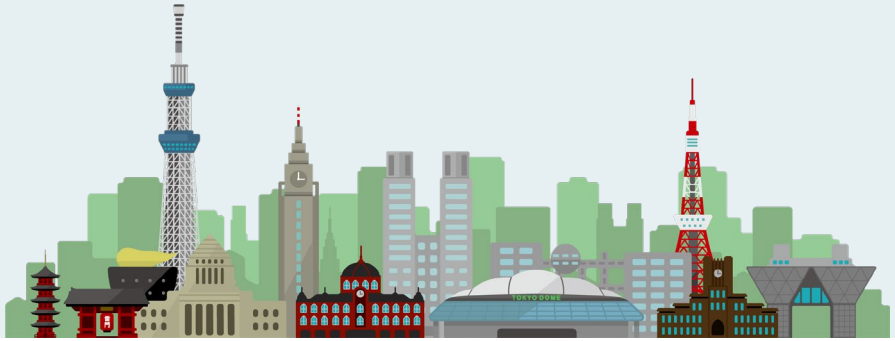
IMDRF International Medical Device Regulators Forum



Regulatory Update - ISP Chile

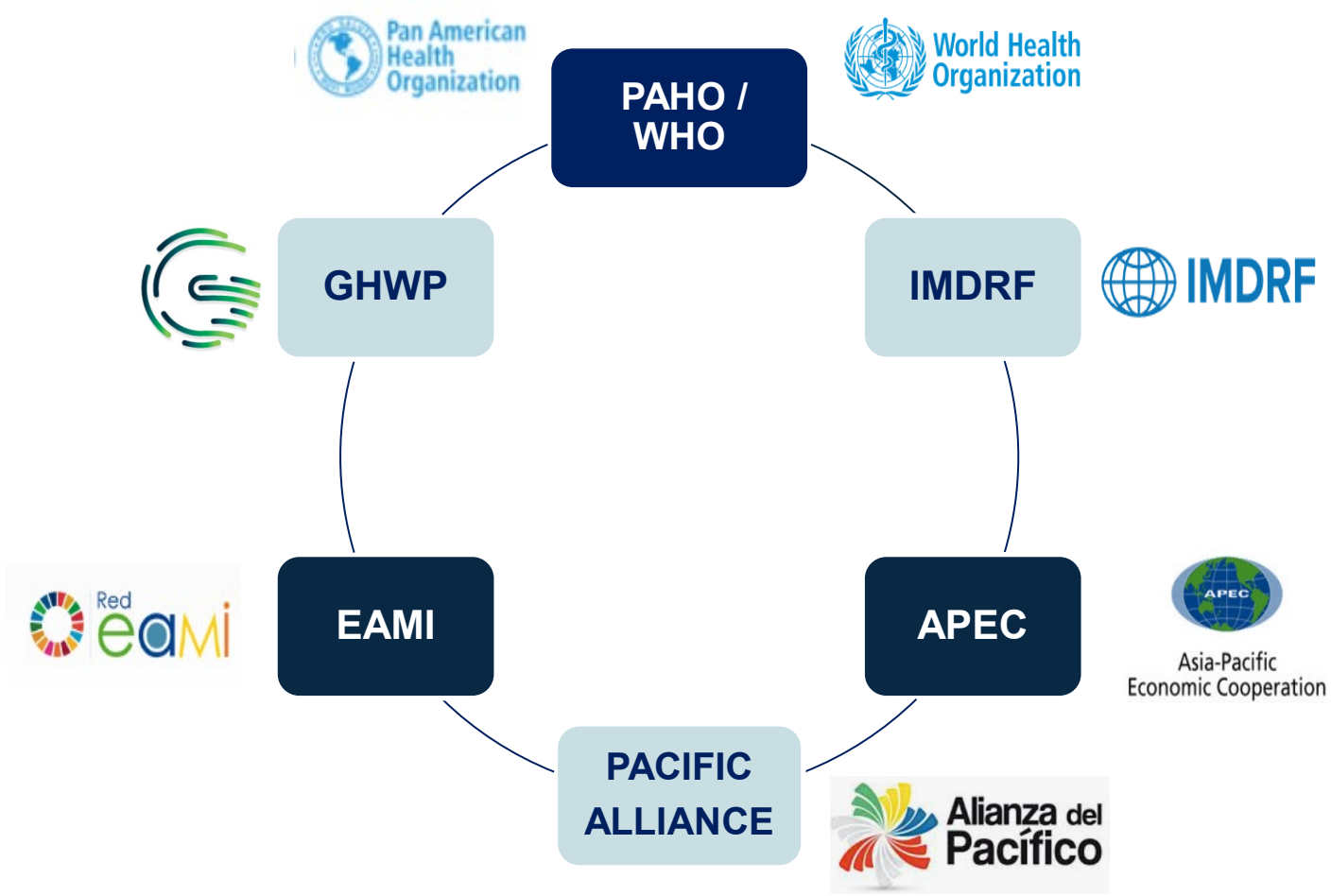
Tokyo, March 2025

María Cecilia López, MPH, Pharm.
Head of Medical Devices Registration Office
Department of Medical Devices, Public Health Institute (ISP) of Chile

I. Introduction about ISP

- The Public Health Institute of Chile (ISP, per its acronym in Spanish) founded in 1892, regulates pharmaceutical/vaccines, medical devices including IVDs, cosmetics, among other functions.
- ISP depends on the Ministry of Health (MoH) for approval of its policies and regulations.
- Strengthening of the MD & IVDs regulatory system has been a priority over the last years.
- Chile is considering the use of the WHO GBT indicators to develop an effective and efficient regulatory system.
- Participation in international harmonization and convergence initiatives offers an important support.

II. ISP International Engagement



- IMDRF Affiliate Member since October 2023.
- Pacific Alliance Member Country since 2011.
- GHWP Member Economy since 2009.
- PAHO Regional Working Group Member since 2002.
- EAMI Member RNA.
- APEC Member Economy.

III. Medical Devices Department Staff at ISP

- Given the diverse nature of MD & IVDs, ISP has a **multidisciplinary staff**: physicians, biomedical engineers, biochemists, pharmacists, medical technologists, phonoaudiologists, physiotherapists, and medical physicists.

- Training and certifications in different international standards, for example:
  - ISO 13485
  - ISO 14971
  - ISO 10993
  - ISO 14155
  - ISO 16142-1 & ISO 16142-2.

- Aligned with WHO GMRF & IMDRF documents.

IV. Relevant Updates since IMDRF Membership

- Capacity Building
- Recient Legislation Changes
- Project to Strengthen MD Regulation & Results

Capacity Building & International Collaboration 2024

- To learn much from what other agencies are doing, including through information exchange.
- ISP delegates visited **ANMAT** (Argentina), **ANVISA** (Brazil) and **INFARMED** (Portugal) in 2024.
- ISP is very grateful for the regulatory knowledge and the experiences shared by these NRAs.

International Participation 2024 other than IMDRF

Training Event	Date	Organizer
WHO Regulatory Training, Spring 2024.	May, 27-31 (In person)	WHO / Swissmedic
2024 APEC Regulatory Sciences, Center of Excellence Workshop.	August, 18-20 (In person)	APEC / TFDA, Taiwan
Aligning Medical Device Regulation to Optimize Risk Management.	September, 15-16 (In person)	APEC / USC, USA
Virtual Course on Medical Devices Regulation, 3rd Edition.	Sept-Dec	CECMED, Cuba
Virtual Course on Health Regulation of Medical Products.	Oct-Dec	PAHO / WHO

Capacity Building – Training by ISP 2024

4

Virtual Courses on Post-Market Surveillance

- 498 Participants (Healthcare professionals)
- May to November 2024

1

Regulatory Training to Local Manufacturers & Academic Researchers

- 42 participants
- November 2024 (In person)

Instituto de Salud Pública — Gobierno de Chile

100 AÑOS SALUD Y SEGURIDAD SOCIAL

Sistema Nacional de Tecnovigilancia

FECHA: 25 de julio 2024
TOTAL HORAS PEDAGÓGICAS: 4
LUGAR: Plataforma Teams

Expositores:
- Químico Farmacéutico, María Cecilia López
- Químico Farmacéutico, Giovanna Benítez González
- Ingeniero Biomédico, Catalina Valdés León

Objetivo del Curso:
Dar a conocer los avances en la conformación de la Red Local de Tecnovigilancia y conocer experiencias de implementación.

Público Objetivo:
Responsables de Tecnovigilancia y sus subrogantes de los Servicios de Salud y Secretarías Ministeriales de Salud del País.

HORARIO	TEMA / EXPOSITOR(A)
9:05 – 9:10	**Palabras de Bienvenida** Dra. Janepsy Díaz Tito Jefa Departamento Agencia Nacional de Dispositivos Médicos, Innovación y Desarrollo (ANDID) INSTITUTO DE SALUD PÚBLICA DE CHILE
9:10 – 9:40	**Dispositivos Médicos y sus Avances Regulatorios** Q.F. María Cecilia López Gutiérrez Jefa Subdepartamento Autorización y Registro de Dispositivos Médicos Departamento Agencia Nacional de Dispositivos Médicos, Innovación y Desarrollo (ANDID) INSTITUTO DE SALUD PÚBLICA DE CHILE
9:40 – 10:10	**Avances en Fiscalización** Q.F. Giovanna Benítez González Jefa Sección Fiscalización Subdepartamento Autorización y Registro de Dispositivos Médicos Instituto de Salud Pública de Chile, Departamento Agencia Nacional de Dispositivos Médicos, Innovación y Desarrollo (ANDID)
10:10 – 10:40	**Avances en Tecnovigilancia y Red Local** Ing. Biomédico Catalina Valdés León Jefa de la Sección de Tecnovigilancia Subdepartamento Autorización y Registro de Dispositivos Médicos Instituto de Salud Pública de Chile, Departamento Agencia Nacional de Dispositivos Médicos, Innovación y Desarrollo (ANDID)
10:40 – 11:00	*Intermedio*
11:00 – 11:40	Experiencias en la Conformación de la Red Local de Tecnovigilancia e implementación de la Norma N° 204 – Q.F. Ana Cristina Osorio Miller y equipo, Servicio de Salud del Reloncaví.
11:40 - 12:20	Experiencias en la Conformación de la Red Local de Tecnovigilancia e implementación de la Norma N° 204 – EU -Iris Vergara Cortés y equipo, Servicio De Salud Metropolitano Norte
12:20 – 12:50	Actividad Interactiva.
12:50 - 13:00	**Palabras de Cierre** M.V. Alejandra Vaquero Orellana Jefa Subdepartamento Vigilancia Sanitaria y Post-Mercado Departamento Agencia Nacional de Dispositivos Médicos, Innovación y Desarrollo (ANDID) INSTITUTO DE SALUD PÚBLICA DE CHILE

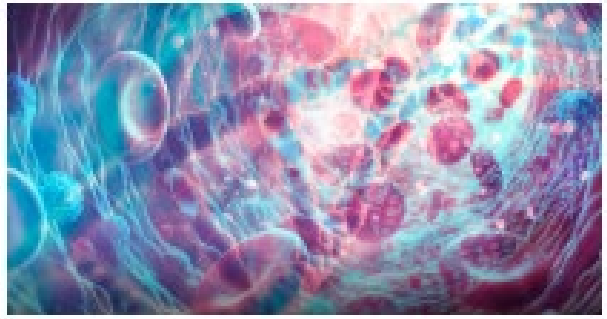
Legislation Changes

A **new Decree,** that specifies regulatory controls, including testing by ISP Reference Laboratory, for **Immunohematology Reagents,** was issued by MoH.

Decree No. 5 of 2025 was officially **published** on **February 21**.

2023 | **2024** | **2025**

Draft Decree was available for **public consultation** at MoH website.



ISP informa sobre nueva normativa que regulará dispositivos médicos de diagnóstico in vitro relacionados a transfusiones de sangre

El Instituto de Salud Pública (ISP) informa que durante febrero se publicó en el Diario Oficial el decreto que regula reactivos inmunohematológicos para análisis de sangre utilizados en el estudio de los antígenos y ...

More information:
https://www.ispch.gob.cl/noticia/rige-norma-que-regula-dispositivos-medicos-utilizados-en-transfusiones-de-sangre/

A new legislative proposal for medical devices

- On **January 30, 2025**, a new legislative proposal was introduced to the Congress.
- The Chilean government is seeking to amend the Sanitary Code Act to modernize the national health system.
- One of its most relevant modifications is to **grant ISP additional faculties** to establish an **updated regulatory framework** of medical devices & IVDs.
- Therefore, there are **significant changes** to the existing regulatory system for a MD & IVDs.

Project to strengthen the medical devices regulation in Chile

- On July 2024, the ISP completed the execution of the Project to Strengthen the Medical Devices Regulation in Chile.
- This project was financed by the Chilean Economic Development Agency (CORFO).

CORFO

Instituto de Salud Pública
Ministerio de Salud
Gobierno de Chile

What did we do?

Gap Analysis of Existing Controls

The **WHO GBT+MD** was used for evaluation of Chilean regulatory system.

Gap Analysis Results

Setting **priorities** for implementation.

Assesment of the **financial resources**.

ISP Implementation Plan 2025-2030

Road map of actions, **timelines** and **deliverables**.

Trained **staff**, **infrastructure & IT**.

V. NEXT STEPS 2025

- **IMDRF Working Groups**
- Increase the ISP participation.
- Interest WG: AET, QMS and GRRP.

- **IMDRF Documents Implementation**
- New final ISP guidances documents published.

- **Implementation of Decree No.5 of 2025**
  (applicable to Inmunohematology Reagents).

- **Public Consultation at ISP Website**
- Guidance documents issued by ISP.
- According to Good Regulatory Practices.

17th Scientific Conferences of ISP

- **13 – 15 May 2025, Santiago, Chile**

- To promote the exchange and reflection about scientific and technological knowledge: regulators, industry, academy and key stakeholders of public health.

- One of the main topics is medical devices regulation & innovation.

More information is available at ISP website:
https://www.ispch.gob.cl/andim/jornadas-cientificas/

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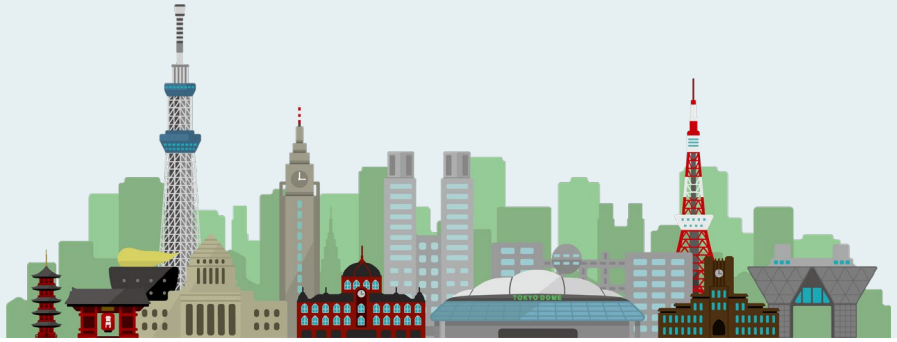

Thank you/Questions

Instituto de Salud Pública
Ministerio de Salud
Gobierno de Chile

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ISP website www.ispch.cl