Regulatory Update - ISP - Chile

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Agenda

- ✓ Public Health Institute and Department of Medical Device
- ✓ Overview of Chilean Medical Device Regulation
- ✓ Relevant Updates
- ✓ Key Elements of Strengthening Post Market Vigilance
- ✓ Challenges

About Us

- The **Public Health Institute of Chile** (ISP, per its acronym in Spanish), founded in 1892, is a public Service which has management autonomy with an own budget and fiscal contribution.
- ISP depends on the Ministry of Health (MoH) for approval of its policies and regulations.
- **Mission**: ISP is responsible for promoting and protecting the public health by strengthening health control through surveillance, authorization, inspection, research and technological transfer; complying with high standards of quality, transparency, innovation and a human team committed to public service.
- **Regulatory functions**:

✓ ISP regulates pharmaceuticals/vaccines, **medical devices (including IVDs),** cosmetics, personal protective equipment (PPE), pesticides and disinfectants.

✓ To meet standards of safety, quality and efficacy.

About Us (Cont.)

ISP Website: https://www.ispch.gob.cl/organigrama/

MEDICAL DEVICES DEPARTMENT
43 persons

Medical Device Department

It was born as a Department in 2017 to develop a new regulatory framework for medical devices and to develop regulatory capacity.

It trains competent staff aligned with ISO 13485, ISO 14971, ISO 10993, ISO 14155, among others, and WHO Global Model Regulatory Framework for MD & IVDs.

It comprises of a **multi-disciplinary staff:** Physicians, Biomedical Engineers, Pharmacists, Biochemists, Medical Technologists, Physiotherapists, Medical Physicists, among others.

It is composed of **4 sub-departments**: (1) Authorization and Registration MD &IVDs, (2) Vigilance and Post-Market Surveillance MD & IVDs, (3) Radiological Health, (4) Innovation, Development & Technological Transfer.

Overview of Chilean Medical Device Regulation

CURRENT STATUS

- MD & IVDs are regulated mainly under the **Sanitary Code** and its **Decree No. 825 of 1998.**
- A **limited regulation for MD & IVDs** currently in place **but with the ambition to improve** this situation.
- Few types of MD & IVDs are subject to mandatory control.
- Voluntary revision of documentation of a medical device not subject to mandatory control.

WINDOW OF OPPORTUNITY

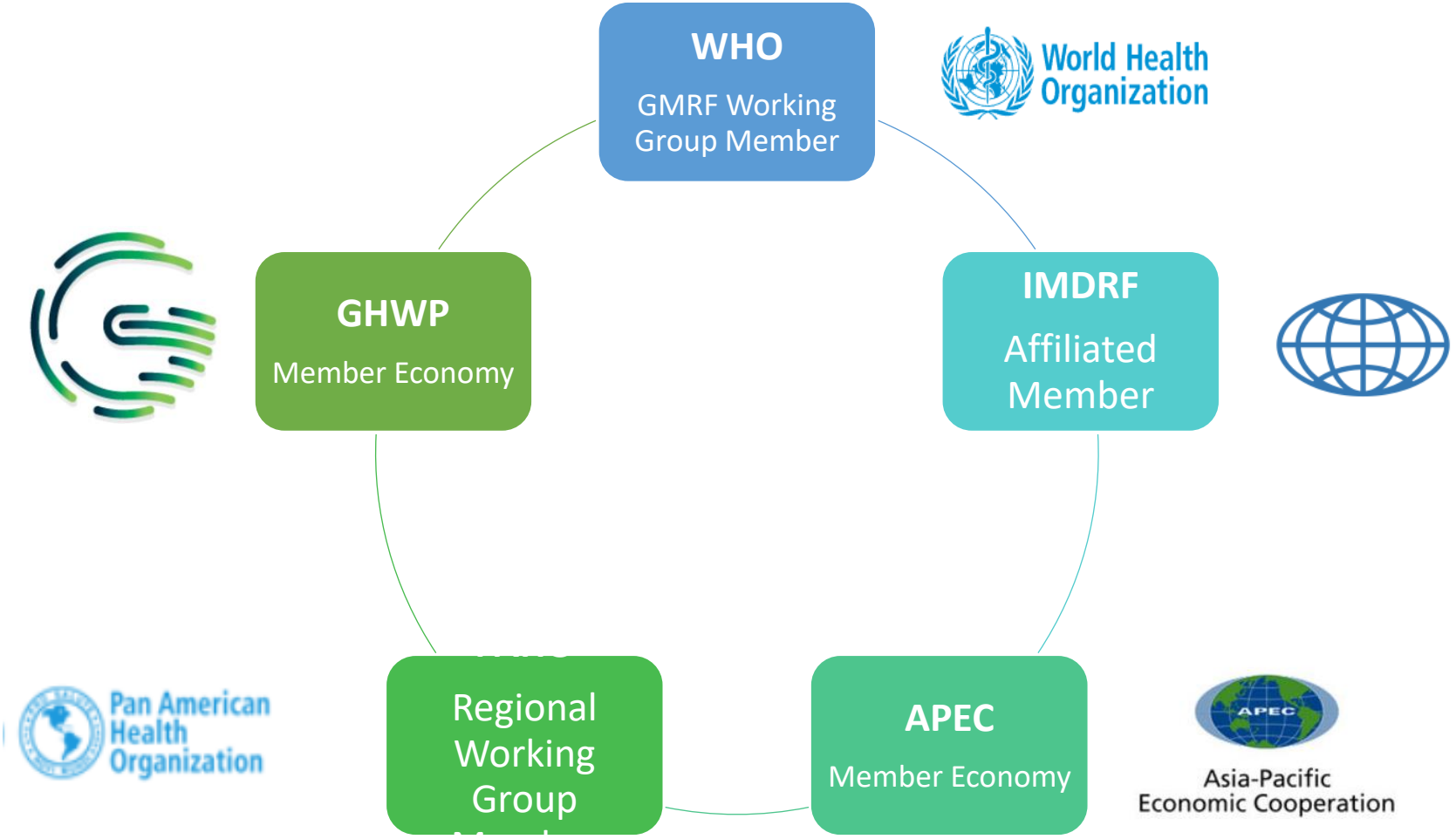
There is currently a **bill of law** under discussion in the Congress that, among other changes, will modify the Sanitary Code regarding medical devices.

- The **creation of the Department of Medical Devices** within the ISP (2017).
- **International Exchange** and **Cooperation** Activities.

FUTURE REGULATION

- All MD & IVDs will be subject to mandatory control.
- A **new framework** for MD (once the law is approved) **will be aligned** with **international regulatory convergence** according to the **IMDRF/GHWP documents** and to the **WHO Global Model Regulatory Framework** for MD including IVDs.

Participation in Global Regulatory Convergence/Harmonization Activities



- ISP is GHWP Member Economy since 2009.
- ISP is IMDRF Affiliate Member since 2023.

Relevant Updates

MAIN INITIATIVES TAKEN:

1. **Development** of **guidance documents** aligned with IMDRF / GHWP / WHO:
   - MD Classification based on risk (June 2018);
   - IVD Classification based on risk (April 2019);
   - Essential Principles of Safety and Performance of MD and IVDs, including Principles of Labelling (March 2019);
   - Clinical Evaluation (December 2020);
   - Technovigilance National System (January 2021);
   - Good Storage, Distribution and Transportation Practices for MD and IVD Medical Devices (January 2022);
   - Borderline MD and IVD Medical Devices (October 2022).

   ISP Website: https://www.ispch.gob.cl/andid/guias-tecnicas-y-material-de-capacitacion/

2. **Working groups** with industry associations to share and discuss the guidance documents.

3. **Training** to the local industry and health-care professionals (e-learning courses, workshops, meetings).

4. **Strengthening** of Post Market Vigilance.

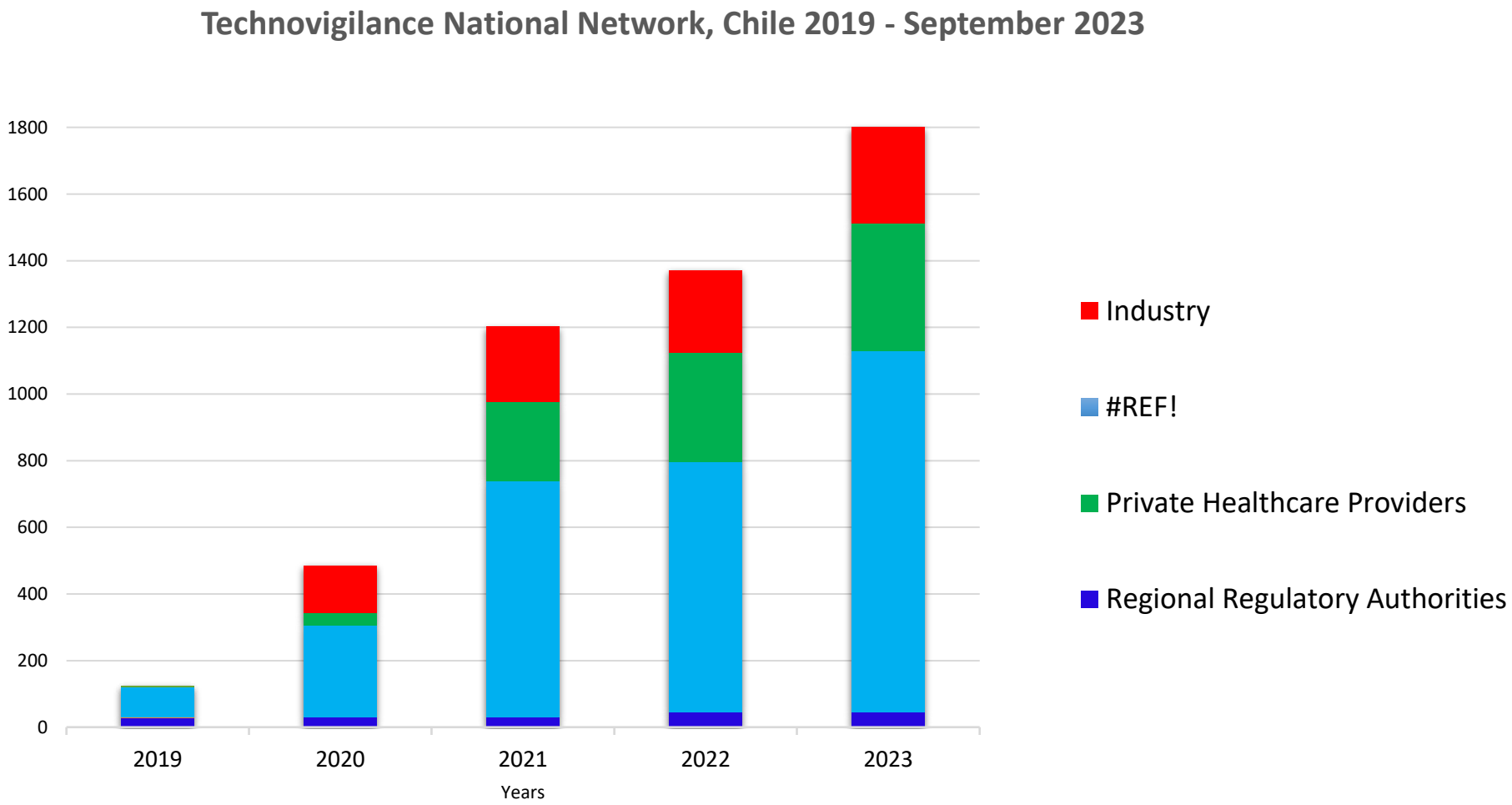
Key Elements of Strengthening Post Market Vigilance

1. Development of Regulation Nº 204: Technovigilance
2. Development of the Technovigilance National Network
3. Systematic Review of Field Safety Corrective Actions (FSCA)
4. Development of Adverse Event Report Platform

1. Development of Regulation Nº 204: Technovigilance

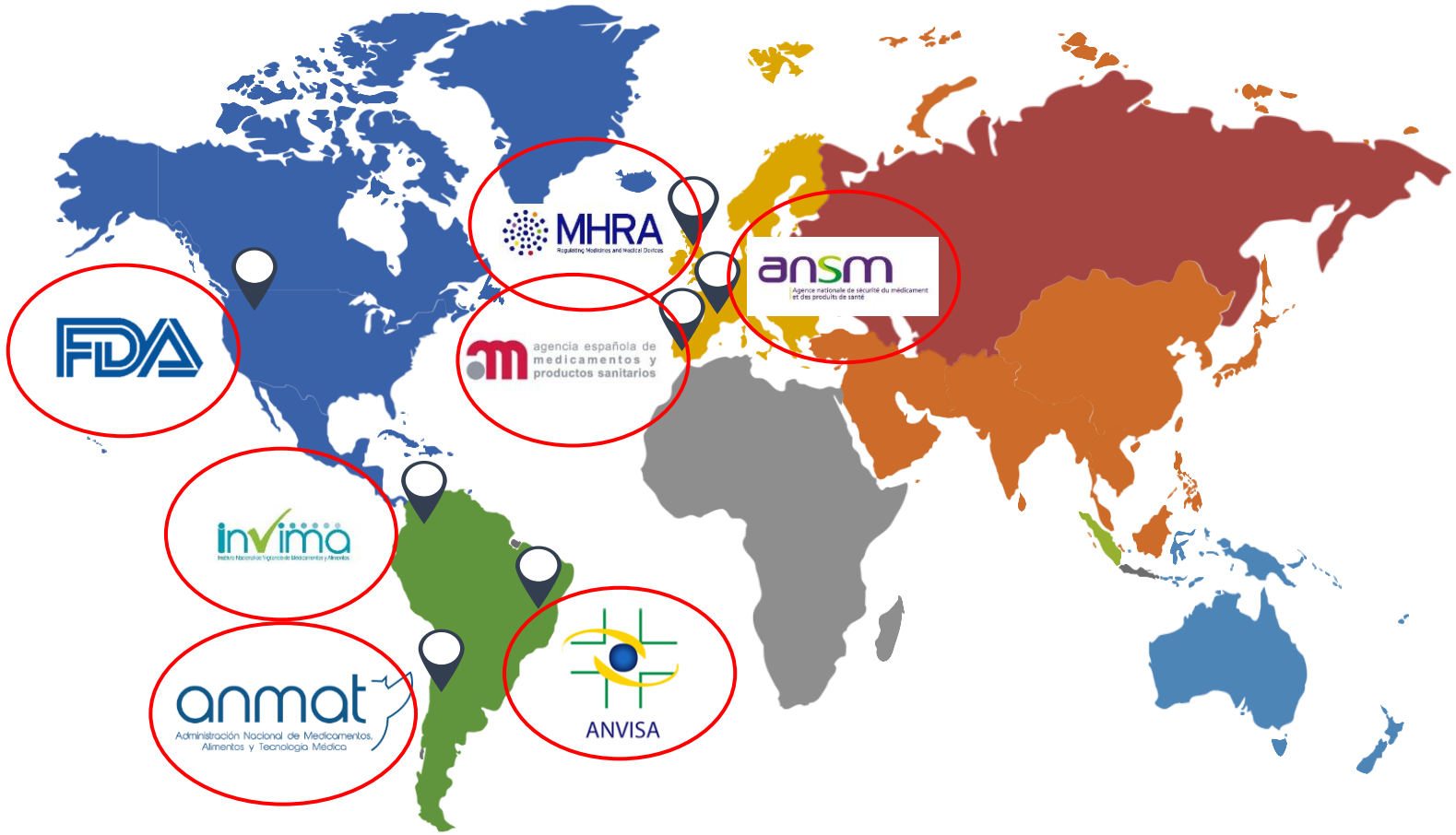
- ✓ Published in 2019 by the MoH
- ✓ Scope: Healthcare Providers
- ✓ Applicable to **all Medical Device** place on the market
- ✓ It establishes the **requirement** to designate a Healthcare Professional in charge of **Technovigilance in every Healthcare Facilities** in the country (National Network).
- ✓ **Mandatory notification** of adverse events by healthcare providers.

2. Development of the Technovigilance National Network



Source: Sección Tecnovigilancia. Instituto de Salud Pública de Chile.

3. Systematic Review of Field Safety Corrective Actions (FSCA)



1. Food and Drug Administration (FDA) – USA
2. Instituto Nacional de Vigilancia de Medicamentos y Alimentos (INVIMA) – Colombia
3. Administración Nacional de Medicamentos, Alimentos y Tecnología Médica (ANMAT) - Argentina
4. Medicines and Healthcare Products Regulatory Agency (MHRA) – UK
5. Agencia Española de Medicamentos y Productos Sanitarios (AEMPS) – Spain
6. Agencia Nacional de Vigilancia Sanitaria (ANVISA) – Brazil
7. Agencia Nacional de Seguridad de Medicamentos y Productos Sanitarios (ANSM) – France

4. Development of Adverse Event Report Platform

- ✓ In November 2022, ISP implemented the **reporting platform**, *"Sistema de Vigilancia Integrada"* (SVI).
- ✓ On this platform, healthcare providers and industry must report adverse events of pharmaceuticals, vaccines, **medical devices (including IVDs)** and cosmetics.
- ✓ With the implementation of this system, it is expected to obtain **standardized databases** that allow monitoring the occurrence of adverse events.
- ✓ **First stage of development:** consequence of the adverse event. (ISO-TS 19218, IMDRF/AE WG/N43FINAL:2020, Edition 4)

Summary of Post Market Vigilance

Adverse Event Report Platform

Systematic Review of FSCA

Regulation Nº 204: Technovigilance

Technovigilance National Network

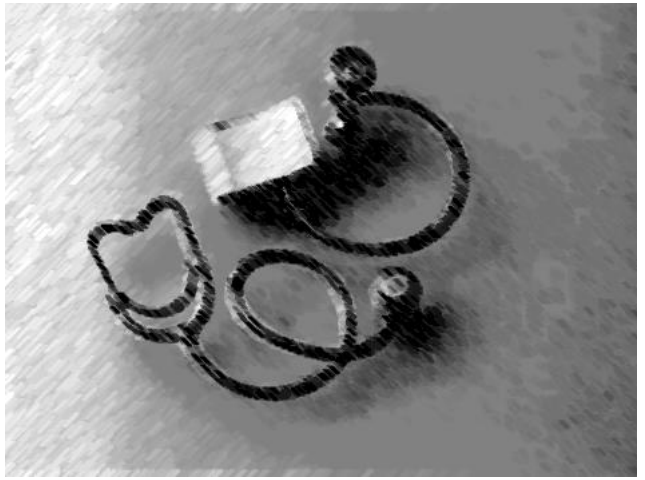
ACTIONS TAKEN

1. **Monitoring the occurrence of adverse events.**
2. **Comunicate FSCA and security information to the Technovigilance Network.**
3. **Publicate alerts in ISP website.**

https://www.ispch.cl/categorias-alertas/dispositivos-medicos/

Challenges

1. Continue building technical and regulatory expertise.
2. Improve the chilean medical devices regulation aligned with international harmonization.
3. Confidence building with other regulatory authorities.
4. Promote convergence in regulatory requirements, with an emphasis on medical devices and innovative technologies.



Thank You / 謝謝

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