Instituto de Salud Pública
Ministerio de Salud

Gobierno de Chile

INSTITUTO DE SALUD PÚBLICA DE CHILE

# CHILE REGULATORY UPDATE

## 21st AHWP Meeting

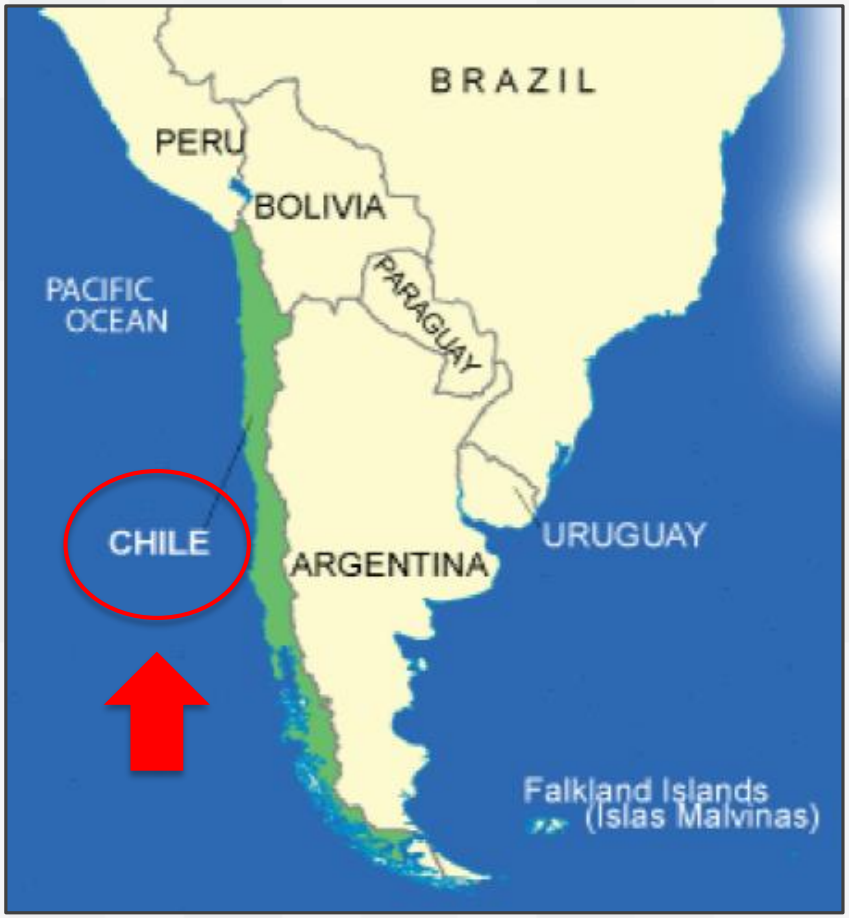
## Cebu, Philippines, 25 November 2016

**MARÍA CECILIA LÓPEZ**
**Medical Device Office**
**Public Health Institute of Chile**
Chile


# AGENDA

1. Overview
2. Current Status
3. Initiatives Taken
4. Future Prospects & Challenges

# 1. OVERVIEW




- Chile is situated on the Pacific Coast of South America and borders Peru, Bolivia and Argentina. The capital is Santiago of Chile.
- The current population in Chile is 18.204.485.
- AHWP Member Economy since 2009.

# CHILE: MEDICAL DEVICE MARKET OVERVIEW

- Strong business environment, receptive to foreign firms operating in the country.
- Among the smallest markets in Latin America.
- Chile has a small medical device industry with low exports.
- With only a small domestic industry, the market is heavily reliant on imports (95,5% supplied by imports)

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# CHILE: MEDICAL DEVICE MARKET OVERVIEW (Con´t)

## Table : Top 5 Medical Device Suppliers, 2014

| | Country | % Total |
|---|---|---|
| 1 | USA | 33,3 |
| 2 | Germany | 14,0 |
| 3 | China | 10,5 |
| 4 | Mexico | 4,1 |
| 5 | Japan | 3,8 |
| 6 | Others countries | 34,3 |

*Source : Chile Medical Devices Report by BMI Research*

# REGULATORY AUTHORITIES

• The Ministry of Health of Chile (Spanish: Ministerio de Salud de Chile) also known as MINSAL, regulates the public and private health sectors.

• The MINSAL is in charge of planning, directing, coordinating, executing and controlling the public health policies.

• Currently under the Ministry is the following public institution: PUBLIC HEALTH INSTITUTE OF CHILE (Spanish: Instituto de Salud Pública, ISP)

• The Public Health Institute has management autonomy and depending on the Ministry of Health for approval of its policies and standards. Mandated to control safety, quality and effectiveness of food, medicines, cosmetics and medical devices (incl. *in vitro* Diagnostics)

# REGULATORY AUTHORITIES (Con´t)

## CONSTITUTION MEDICAL DEVICES OFFICE:

Team that includes biochemists, biomedical engineers, pharmacists, medical technologists and a secretary.

# CONSTITUTION MEDICAL DEVICES OFFICE (Con´t)

**Since 2014: Creation of a Committee of External Technical Experts from Chilean Scientific Societies to work in coordination with Medical Devices Office.**

**Mr. Guillermo Avendaño**
Biomedical Engineer

**Mr. Lientur Taha**
Neurosurgeon

**Ms. Irene Fuentes**
Nurse

# 2. CURRENT STATUS

- **Not all medical devices are regulated in Chile.**
- **Proposed a second amendment to the law that includes a harmonized medical devices regulatory system:**

✓ Definition MD & IVDDs
✓ Classfication based on risk
✓ Nomenclature
✓ Standards of medical devices
✓ Premarket control and review (Registration and licencing))
✓ Laboratory testing (specific cases)
✓ Quality management systems requirements
✓ Clinical investigation
✓ Post Market Surveillance and Vigilance

- **All Medical Devices will be regulated under the proposed Law.**
- **Status of proposed Law: discusing on the Parliament for consideration since April 2016.**

# 3. INITIATIVES TAKEN

**1. Training and continuining education of Medical Devices Team to enhance its expertise:**

- ✓ ISO 13485 QMS
- ✓ ISO 10993 Biocompatibility
- ✓ ISO 14971 Risk Assessment
- ✓ IEC 60601 Electrical Safety
- ✓ Good Distribution and Storage Practice for Medical Devices

**2. Training and education to the local industry:**

- ✓ Dec 2013: Workshop to promote ISO 13485
- ✓ Apr 2016: Workshop to promote regulatory convergence

Both Workshops were organized by the Medical Devices Office and the Scientific Medical Devices Society (SCDM)

**3. Training and education to the Health professionals from public hospitals. Featuring ISP professionals:**

- ✓ 2015 and 2016: E-learning Course to provide the guidelines and tools about medical devices regulation and adverse event/problem reporting.

# 3. INITIATIVES TAKEN (Con´t)

**4. Guidance documents aligned with AHWP & GHTF/IMDRF published on the website**

- ✓ Guidance for Medical Device Classification based on risk.
- ✓ Guidance to purchasing medical devices used in hospitals and clinics.
- ✓ Guidance for Vigilance: Detail requirements for industry, health professionals and users on adverse reporting system.

**5. Guidance documents in process of drafting and finalization aligned with AHWP & GHTF/IMDRF**

- ✓ Guidance for Good Distribution and Storage Practice for Medical Devices.
- ✓ Guidance for preparation of a submission dossier Medical Devices Class III y IV.
- ✓ National Plan of Surveillance.

**6. Regulation for Medical Device and Medicines Clinical Evaluation in process of drafting**

- ✓ Proposed document published on the Ministry of Health website for public consulting until November 25, 2016.

# 3. INITIATIVES TAKEN (Con´t)

## 7. International Exchange

- ✓ Medical Devices Team participate at AHWP, APEC, IMDRF and PAHO meetings.
- ✓ Medical Devices Team participate at Pan American Health Organization (PAHO) Regional Working Group and actively engaged in Mirror Working Group on the NCAR Exchange Program: REDMA Program.
- ✓ Exchange and dialogs with regulators and others countries:
- ❑ In country capacity training with regulators from Cuba and Spain.
- ❑ Participation in teleconference organized by ANMAT, Regulatory Authority of Argentina.

# 4. FUTURE PROSPECT & CHALLENGES

- Approval by Parliament of the amendment of the law to provide an effective regulation of medical devices.

- New Medical Devices Law with three (3) aspect for robust regulation:

✓ Premarket control
✓ Quality system
✓ Post market Surveillance

- Progressive implementation of the new regulations.

- Stakeholder – regulators communication.


# Thank you for your attention!

mclopez@ispch.cl