CHILE REGULATORY UPDATE

17th AHWP Meeting
Chinese Taipei, 05 November 2012.

Instituto de Salud Pública
Ministerio de Salud

Gobierno de Chile

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AGENDA

1. Overview
2. Regulatory Authorities
3. Legal Regulation
6. Legislative Modernization
7. Future Prospects & Challenges

OVERVIEW

Capital : Santiago de Chile

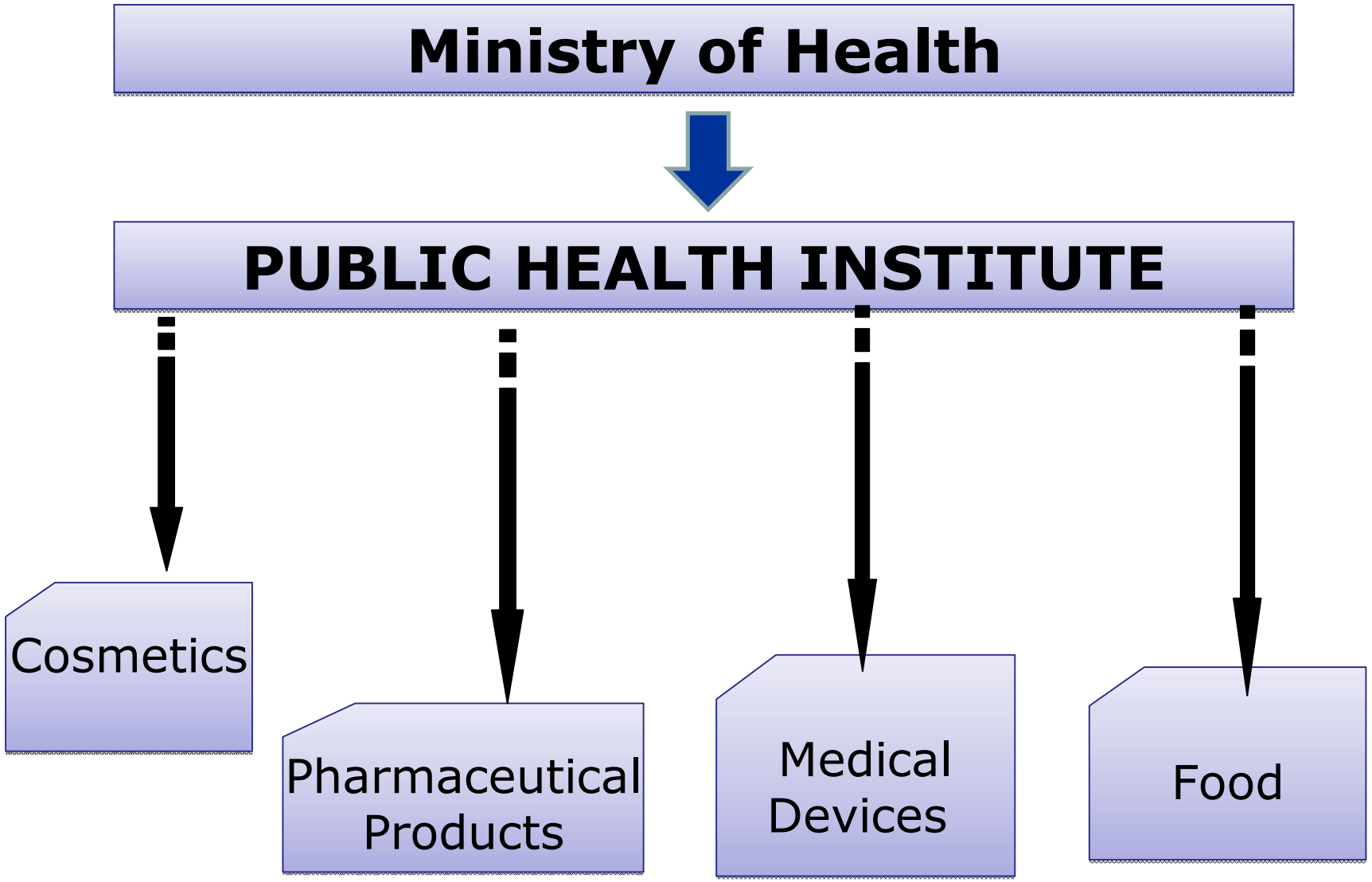
Population: ~ 17.000.000

Official Language: Spanish

Medical Devices Market: ~ 80% importer

The main supplier is USA : ~ 40%

REGULATORY AUTHORITIES



MEDICAL DEVICES OFFICE

Medical Devices Office is responsible for the regulation of medical devices on the chilean market.

LEGAL REGULATION

1997: MEDICAL DEVICES AFFAIRS ACT N°19.497 - Ministry of Health

1998: MEDICAL DEVICES AFFAIRS FRAMEWORK N° 825 - Ministry of Health

INTERNATIONAL TRAINING

Regulatory Event	Place/ Date
The 14th, 15th, 16th y 17th Asian Harmonization Working Party (AHWP) Meeting"	- Taiwan, 2 - 6 Nov 2012 - Arabia Saudita, 27 Nov-01 Dic 2010 - Indonesia, 8 - 12 Nov 2011 - Hong Kong, 4 - 7 Nov 2009
OPS "Health Products and Food Branch (HPFB) International Regulatory Forum"	Canadá, 24-28 de September 2012
Reunión de las Autoridades Reguladoras para el fortalecimiento de la capacidad reguladora de los dispositivos médicos en la región de las américas	Cuba, 10-12 July 2012
APEC "Good Review Practice Workshop on Medical Products"	China Taipei, 11-14 October 2011
"Programa de Cooperación de Apoyo a la regulación de productos Médicos" ANMAT	Argentina, 8-12 August 2011
APEC "2011 AHC Workshop on Medical Devices: Implementation of GHTF Documents"	Corea, 4 - 5 July 2011
APEC "Principles for voluntary Codes of Business Ethics to ensure ethical interactions between medical technology Company and Healthcare Professionals"	Malasia, 6 - 7 April 2011
"APEC – Funded Delegation Visit to Canada and the United States"	Canadá & USA, 08 - 18 de August 2010

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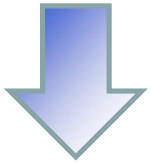
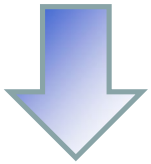
INTERNATIONAL COOPERATION

- APEC : member economy since 1994
- AHWP : member economy since 2009



✓ Link with the global harmonization
✓ Understand of key elements regulatory model
✓ Communication with other regulatory autorithies
✓ Training



There is a need to get an updated framework

CURRENT STATUS IN CHILE

5 Types of Medical Devices are regulated

Medical Devices Class III y IV are not regulated

(High Risk)

¿Public Health Protection?

CURRENT REGULATORY MODEL

Demands:

- Local quality control (**imported** & manufactured MD)
- Third parties certification (Local)

However according to the international recommendations to countries **mainly importers**, it should be:

- Recognize international certifications (ISO 13485, ISO 14971, etc)
- Avoid duplicative quality control

LEGISLATIVE MODERNIZATION

- **Medical Devices Affairs Act <u>Amendment</u>**
  → Chilean Parlament
  (Hopefully approved on December 2012)

- **Medical Devices <u>Framework UPDATED</u>**
  → according to AHWP & GHTF´s recommendations
  (1st Draft on December 2012)

- Work in close collaboration with MD industry

FRAMEWORK UPDATED: Key Elements

- ✓ Harmonized definition of a medical device: MD & IVDs
- ✓ Classification of medical devices according to risk level: MD & IVDs
- ✓ Registration of manufacturers, distributors and importers and listing.
- ✓ Pre-market Evaluation:
  - Essential Principles of Safety & Performance of Medical Devices
  - Recognize of international standards
- ✓ Post-Market Surveillance/Vigilance
- ✓ QMS requirements
  - Recognize ISO 13485
- ✓ QMS auditing
- ✓ Control of Clinical Trials
- ✓ Control of advertising and promotion

FUTURE PROSPECTS & CHALLENGES

- Medical Devices Affairs Act amended *(Dec 2012)*
- Public consultation 1st draft framework *(March 2013)*
- Draft discussed with stakeholders
- Framework approved by Ministry of Health *(hopefully 2014)*
- Progressive implementation framework updated
- Adopt dossier template for registration submission (STED/CSDT)
- Adopt a MD nomenclature system (GMDN/UMDNS)
- Take an active role at AHWP working groups


Thank You!
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