CHILE REGULATORY UPDATE

17th AHWP Meeting
Chinese Taipei, 05 November 2012.

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

1998: MEDICAL DEVICES AFFAIRS FRAMEWORK N° 825 - Ministry of Health
<table>
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| **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 |
<p>| OPS “Health Products and Food Branch (HPFB) International Regulatory Forum”   | Canada, 24-28 de September 2012                                           |
| <strong>Reunión de las Autoridades Reguladoras para el fortalecimiento de la capacidad reguladora de los dispositivos médicos en la región de las américa</strong> | Cuba, 10-12 July 2012                                                    |
| <strong>APEC “Good Review Practice Workshop on Medical Products”</strong>                  | China Taipei, 11-14 October 2011                                          |
| “Programa de Cooperación de Apoyo a la regulación de productos Médicos” ANMAT | Argentina, 8-12 August 2011                                                |
| <strong>APEC “2011 AHC Workshop on Medical Devices: Implementation of GHTF Documents”</strong> | Corea, 4 - 5 July 2011                                                   |
| <strong>APEC “Principles for voluntary Codes of Business Ethics to ensure ethical interactions between medical technology Company and Healthcare Professionals”</strong> | Malasia, 6 - 7 April 2011                                                |
| <strong>“APEC – Funded Delegation Visit to Canada and the United States”</strong>          | Canada &amp; USA, 08 - 18 de August 2010                                     |</p>
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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 authorities
- 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?
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
Medical Devices Affairs Act Amendment
→ Chilean Parliament
(Hopefully approved on December 2012)

Medical Devices Framework UPDATED
→ 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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