

Panel Discussion:
**Unique Legal, Cultural, and Industry
Factors Prevailing in Developing Local
Voluntary Codes**

CHILE - Ms. Giovanna Benitez

President

Scientific Society of Chilean Medical Devices (SCDM)

Agenda

1. Who is SCDM?
2. Legal Factors Prevailing Developing Local Voluntary Codes.
3. Cultural and Industry Factors Prevailing Developing Local Voluntary Codes.
4. Cultural and Industry Factors Prevailing Developing Local Voluntary Codes.

Scientific Society of Chilean Medical Devices (SCDM)

- Is the only Medical Association of professionals and Medical Device Companies that exists in Chile.
- It is an association that has been recently formed (less than a year)
- Approx. 30 members: 70% Transnational companies and 30% National companies.
- It is considered as a counterpart in matters regulated by the Sanitary Authority (ISP).
- ***Their main objective is to train regulators and regulatees in regulatory and ethical matters.***

Legal Factors Prevailing Developing Local Voluntary Codes

1. Legal parameters necessary for the regulation of ethical conducts related to HCP's versus the Industry that can control and punish non-ethical conducts, are non-existent.
2. There are legal asymmetries for the defense of the patients rights with regards to their legal access of information and decisions.
3. Regulatory parameters of Medical Devices is just emerging, meaning that Pre and Post commercialization controls are not efficient.

Cultural Factors Prevailing Developing Local Voluntary Codes

1. Corruption Index: Chile has one of the lowest indexes in Latin America, which makes it easier to voluntarily adopt ethical codes.
2. Commercial transactions between Companies and government HCP's: There is total transparency due to the creation of the Chilecompra platform.
3. HCP Factors : The establishment of constantly receiving personal or institutional benefits over scientific evidence.
4. Patient Factors: The lack of information makes the patients consider a medical decision as indisputable.

Industry Factors Prevailing Developing Local Voluntary Codes

1. Medical devices characteristics: They are products with great innovation that many times require specific training for their use.
2. Multinationals vs National Companies: They respond to international law, which in general, have codes of ethics within their commercial interactions.
3. Medical Associations: In Chile they will have a predominant role in the adoption of Ethical Codes.