Inter-American
Coalition for
Regulatory Convergence
MEDICAL TECHNOLOGY SECTOR

# Structure and Evolution of Health Regulation of MDs in Peru

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# Medical Devices

# Social or economic goods?

Pharmaceutical Product ≠ Medical Devices

# General Health Law N° 26482 - July 1997

- Chapter III – Pharmaceutical products and galenic, and natural therapeutic resources (26 articles)
- Chapter IV – Food and drinks, cosmetics and similar, supplies, instrumental and equipment for medical, surgical or dental use, personal care product and domestic hygiene products (7 articles)
  - Automatic authorization, 7 days for issuing the document
  - Free Sala Certificate and use, issued by country of origin or exportation
  - Surveillance in the market

Rules for registration, control and sanitary surveillance for pharmaceuticals products and related D.S. N° 010-97-SA

- Related - supplies, instrumental and equipment for medical, surgical or dental use

Focus on market? Impact evaluation on public health?
Medical devices are less important than drugs in the sanitary system?

# Pharmaceutical products, medical devices and sanitary products Law N° 29459 - November, 2009

- Principles of Safety, efficacy, quality, rationality, accesibility, social godos, objectivity and transparency
- Definition of pharmaceutical products, medical device and sanitary products
- Require Good practices (manufacturing, Storage, pharmacovigilance, technovigilance, etc.)
- Chapter XIV – Special rules for medical devices
- Risk class clasisfication
- Recognize international organization of reference (GHTF or IMDRF)

Rules for registration, control and sanitary surveillance of pharamecutical products, medical devices and sanitary products - D.S. 016-2011-SA

D.S. 029-2015-SA – Modifies some articles related with medical devices of D.S. 016-2011-SA

Focus on safety and efficacy?
Principles of the law are complied?
How impact requirements not aligned with international and reference norms?

# Opportunities

- Registration by manufacturer vs Registration by manufacturing site
- Country of Origin vs Country of Manufacturing site
- Certificate of Analysis (according to pharmaceuticals products criteria)
- Notification for medical devices risk class I
- Mechanism for impact evaluation of evolving regulation in reference countries (EU MDR / FDA) and adoption ways

# Thank you