Inter-American
Coalition for
Regulatory Convergence

MEDICAL TECHNOLOGY SECTOR

Regulatory cooperation: Facilitating access to medical technologies

WTO – Trade and Public Health Virtual Course
Public Webinar

2 June 2021

Inter-American
Coalition for
Regulatory Convergence
MEDICAL TECHNOLOGY SECTOR

What is the Coalition about?

Vision:
One Standard, One Test accepted everywhere

- Countries: 10
- Principal Members: 17 regional associations
- Member Companies: over 3,000
- Continuous dialog with National Regulatory Authorities for Medical Devices
- Advocating for the use of International Standards: ISO, IEC, etc.

COVID-19 Medical Devices* Examples

- Personal Protective Equipment (PPE)
- N95 face masks
- Gloves
- Hospital gowns and drapes
- Sanitizers
- Respiratory support devices
- *In Vitro* Diagnostics, i.e. PCR Confirmatory Tests
- Components to be re-exported to become finished medical device products
- Medical equipment required to manage complications associated with the illness

**Medical Device Definition: GHTF/SG1/N071:2012, referred by IMDRF AT IMDRF/SAMD WG/N10final:2013*

Inter-American
Coalition for
Regulatory Convergence
MEDICAL TECHNOLOGY SECTOR

COVID-19 Challenges for Medical Devices*

General Challenges

- Underutilizing recognition (pre and post market)
- Lack of electronic review systems and labeling
- Often improperly regulating MD/IVD as pharmaceuticals
- Regulatory Authority and capacity
- Underutilizing risk-based approach (e.g., product modifications)
- Hundreds of thousands of components that change every 18 months
- Global supply chain
- TBT awareness and compliance in the MedTech regulatory processes
- Adoption of Good Regulatory Practices (GRP)

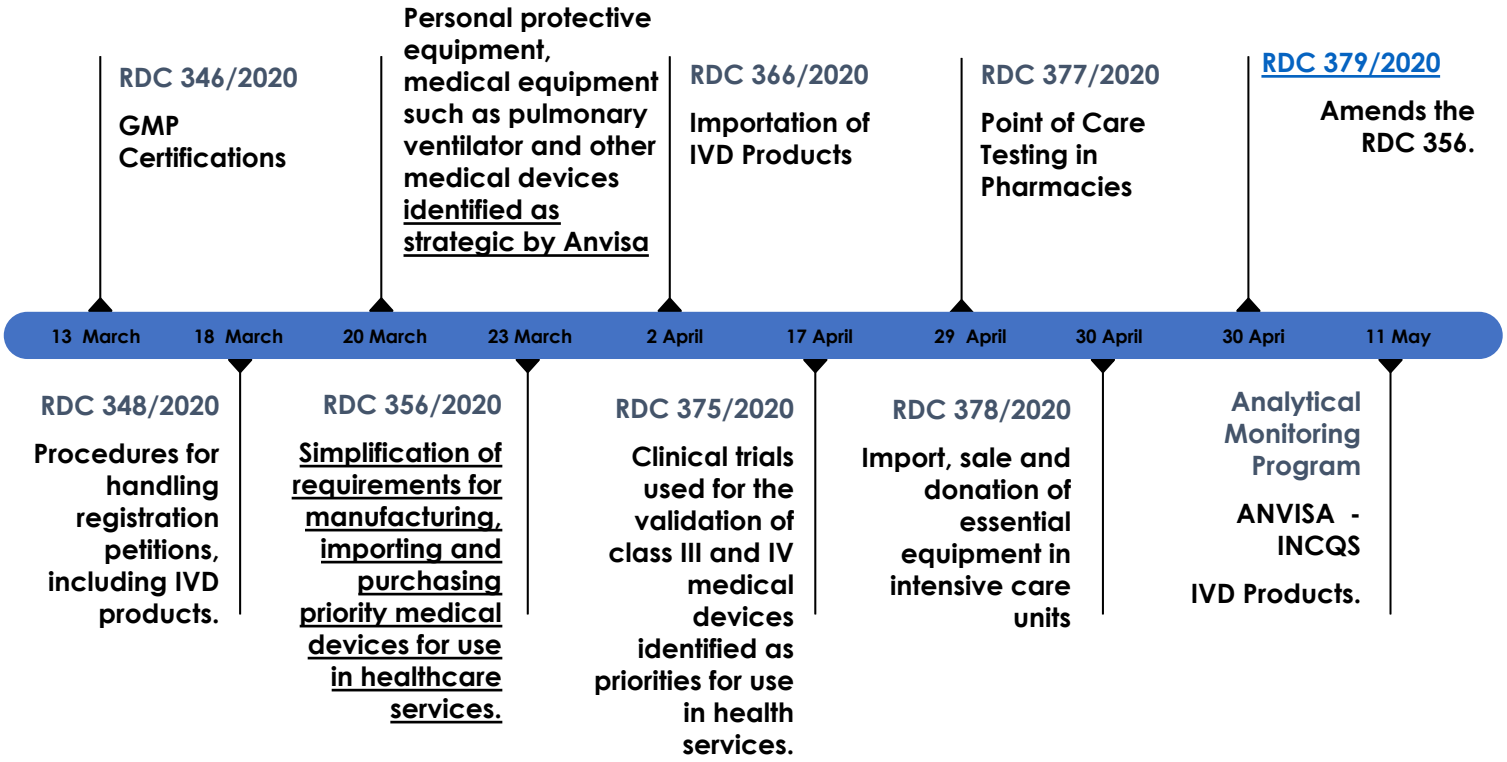
Additional COVID-19 Challenges

- **Lack of emergency use pathways, collection/use of Real- World Data (RWD) while maintaining patient safety**
- **Regulatory Authority remote work, agility, capacity, protocols, and authority**
- **Pandemic leaving other diseases untreated or delayed – long term impact on healthcare sustainability**
- **Regional capacities**
- **National vs sub-national coordination and enforcement**
- **Patchwork of designations as "essential industry"**
- **Government Procurement & Transparency**

** GHTF/SG1/N071:2012, REFERRED BY IMDRF AT IMDRF/SAMD WG/N10final:2013*

Inter-American
Coalition for
Regulatory Convergence
MEDICAL TECHNOLOGY SECTOR

Regulator Actions - ANVISA



Inter-American
Coalition for
Regulatory Convergence
MEDICAL TECHNOLOGY SECTOR

The Size of the Challenge

0 The number of LatAm Countries that have a written policy that implements the TBT agreement within the national regulatory processes for Medical Devices

0 The number of LatAm Medical Device Regulatory Authorities that formally and specifically recognize the WTO/TBT definition of “Technical Regulation”, “Standard” and “Conformity Assessment*

* Not even at the latest published Quality Infrastructure Law in Mexico

Inter-American
Coalition for
Regulatory Convergence
MEDICAL TECHNOLOGY SECTOR

The Size of the Challenge

1

The number of LatAm Medical Device Regulatory Authorities that have implemented the WHO Recommendations for Model Regulatory Framework and Regulatory Reliance for Medical Devices*

3

The number of LatAm Medical Device Regulatory Authorities engaged in international medical device regulatory convergence initiatives**

* Brazil, except for Conformity Assessment
** Brazil, Argentina and Colombia

Inter-American
Coalition for
Regulatory Convergence
MEDICAL TECHNOLOGY SECTOR

The Size of the Challenge

10

The number of LatAm Medical Device Regulatory Authorities that still require a Consularized Apostille of an **original paper document** confirming information **already available online**.

The Size of the Challenge

5 – 50

Vs.

2,000

The number of LatAm Medical Device Regulatory Authorities Staff responsible for Medical Devices Vs. USFDA's CDRH Staff.

Urgent Recommendations

- **Documentation and regular reporting to WTO on:**
  - Implementation of GRP Policy and related SOPs by Health Regulators
  - Implementation of Recognition and Reliance for pre-market and post market activities – WHO Guidance
- **Regulatory processes standardization:** Adoption international best practices
- **Emergency Convergent Pathways for pre-market authorizations and post-emergency management**

Inter-American
Coalition for
Regulatory Convergence
MEDICAL TECHNOLOGY SECTOR

Thank you!

Renata Amaral

Technical Secretariat – Staff Lead on International Trade & GRP

Inter-American Coalition for Regulatory Convergence for the Medical Technology Sector

renata@interamericancoalition-medtech.org