

# MedTech Trade Update & Context

7 May 2025



INTER-AMERICAN COALITION FOR

# REGULATORY CONVERGENCE

MEDICAL TECHNOLOGY SECTOR

ANNIVERSARY



# Patient Barriers to MedTech

- Tax/Tariffs
- Customs/Import Licensing
- ➔ • Regulatory (Including Standards & CA)
- Access/Payment/Reimbursement/Procurement
- Ethics

# Trade Barriers in 4 Numbers

5% - Average Global Import Tariffs (pre-2025)

10% - Inefficient Customs Costs – Tariff Equivalence (NTB)

➔ 20% - Duplicative Regulatory Costs – Tariff Equivalence (NTB)

10-30% - Ethics Costs – Tariff Equivalence (NTB)

NTBs = 40-60% Tariff Equivalence (8-12 times tariff average)

# Trade Barrier Lowering Mechanisms

- Tariffs – Tariff Negotiations / MFN & Agreements
- Customs – WTO Trade Facilitation Agreement (TFA)
- ➔ • Regulatory – WTO Technical Barriers to Trade Agreement (TBT)
- Procurement – WTO Government Procurement Agreement (GPA)

# Technical Barriers to Trade (TBTs)

## (Challenge)

- **Duplicative Regulatory Costs** derive from:
  - **National Technical Regulations** that are:
    - **Overly-Trade Restrictive** because they are not based upon:
      - **International Standards and**
      - **Global Conformity Assessment Procedures**
    - And may therefore constitute **Technical Barriers to Trade (& Health!)**
      - Which are **Non-Tariff Barriers**

# Technical Barriers to Trade (TBTs)

## (Solution)

- **Duplicative Regulatory Costs** may be minimized by having:
  - **National Technical Regulations** be:
    - **Not More Trade Restrictive than Necessary** by being based upon:
      - **International Standards and**
      - **Global Conformity Assessment Procedures**
    - Thereby preventing and removing **Technical Barriers to Trade (&Health!)**
      - Which are **Non-Tariff Barriers**

# Technical Barriers to Trade (TBTs)

## Recommendations (Private Sector)

- Familiarize yourself with the WTO/TBT Agreement
- Use ePing system
- Submit Comments / Develop Specific Trade Concerns
- Be engaged in international and national medtech standardization efforts
- Include TBT, Standards and Conformity Assessment considerations in domestic public consultations and engagements with regulatory authorities
- Be coherent: Align local comments with global comments

# Technical Barriers to Trade (TBTs)

## Recommendations (Public Sector)

- Implement whole-of-government Good Regulatory Practice (GRP) policies
- Implement Standard Operating Procedures within Regulatory Agencies and Government Bodies that implement GRP and TBT commitments
- Be engaged in international and national medtech standardization efforts
- Base national Technical Regulations and Conformity Assessment Procedures on International Standards and Global Practices
- Notify all draft and final measures to the WTO
- Modify draft measures based on comments received to comport with WTO



# Continued Request for Collaboration

## Help us minimize barriers!

- To Medical Technology Trade
- To Medical Technology Market Authorization
- To Medical Technology Supply Chains
- To Global Health Systems
- To Global Health Emergency Preparedness
- To Patient Access!



# THANK YOU

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