Health Perspectives

Access to Medical Devices in the Americas

Trade & Regulatory Aspects

Tariff Equivalents

5, 10, 20, 20

Tariff Equivalents

5%

Average Global Tariffs

- all products

Tariff Equivalents

10%

Customs Inefficiencies

Tariff Equivalents

20%

Non-Tariff Barriers (NTBs)

Tariff Equivalents

10-30%

Unethical Business Practices

AdvaMed Global Priorities

Improve Patient Access to Care

- Minimize Health Market Bottlenecks and Barriers (10%)
- Promote Regulatory Coherence and Convergence (20%)
- Strengthen Ethical Business Practices (10-30%)

Trade Facilitation

Brazil Case Study

- 2016 peak import time for MD – 60 business days
- USD 200 million ~ BRL 660 million
- Cooperation with GOB / ANVISA
- As of November 2018 – times now 3-5 days

Ethics & Compliance

Inter-American
Coalition for
Business Ethics
MEDICAL TECHNOLOGY SECTOR

- Bogotá Principles
- High-standard international ethical business practices for all stakeholders in the Western Hemisphere that operate within or interact with the medical technology sector.

- Includes industry collaboration with healthcare professionals, ethical third party intermediary relationships, and the role of governments as positive enablers in fostering high-standard ethics in the health system.
- The Coalition's mission is to realize full implementation of the Bogotá Principles across the Americas.

Summit of the Americas

Regional Trade – GRP – Ethics

Trade Ministers – Business Federation – Medical Device Luncheon
April 13, 2018 – Lima, Peru

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Good Regulatory Practices (GRP)

- GRP – Regulatory Process Quality, Efficacy and Efficiency
- Tier 1: Foundational GRP – Cross-Sectoral
- Tier 2: Medical Device Regulatory Convergence: Capacity Building, GRP, Model Frameworks, Technical Regulations, Standards, Conformity Assessment requirements

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Tier Structure

- Phase 1: Identify set of international best practices
- Phase 2: Conduct GAP analysis
- Phase 3: Work with individual governments to address/fill gaps
- Phase 4: Work with interested governments together / regional benchmarking

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Project Progress – Tier 1:

- Tier 1 – Phase 1: 100% Complete
  - GRP Policy / Implementation Guide (English, Spanish, Portuguese)
- Tier 1 – Phase 2: 100% Complete
  - GRP GAP Analysis (Colombia, Costa Rica, Mexico, Peru)
- Tier 1 – Phase 3: 100% Complete (initiation and buy in)
  - Bilateral Cooperation: (CRR, industry: Colombia, Costa Rica, Mexico, Peru)
- Tier 1 – Phase 4: 98% Complete (initiation and buy in)
  - Multilateral Cooperation (CRR, industry: Colombia, Costa Rica, Mexico, Peru)

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Tier 1 – Phase 1: GRP International Benchmark

- Good Regulatory Design Document
  - Core elements: OECD, WTO/TBT, APEC, U.S. OMB-A119
  - GRP Checklist (12 items)
  - RIA Checklist (16 items)
  - Policy Primer
    - Including Central Regulatory Review (4 key functions)
  - Spanish / Portuguese

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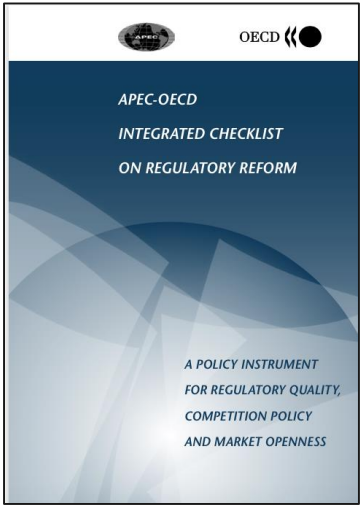
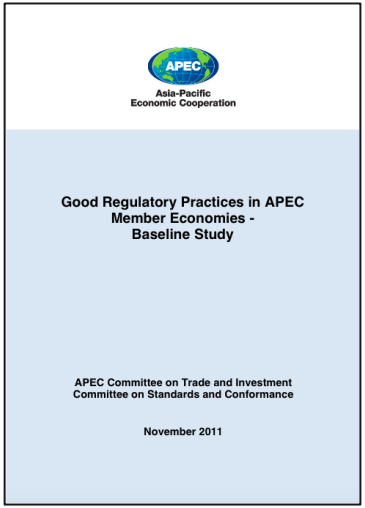
GRP International Benchmarks





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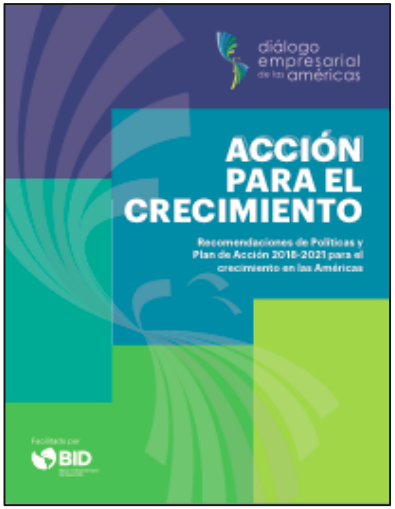
GRP International Benchmarks



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Tier 1 – Phase 1: GRP International Benchmark (continued)

- Implementing Good Regulatory Practices
  - Transparency & Stakeholder Engagement
    - Regulatory Forecast
    - National Regulatory Register
    - Opportunity for Public Comment
    - Publication of Evidence / Regulatory Analysis
    - Respond to Stakeholder Input
  - Other
    - Use of Quality Data & Sound Science
    - Risk-Based Approach
    - Regulatory Impact Assessment
    - Pro-Competitive Analysis
    - Assessment of International Impact
    - Use of international standards and conformity assessment
    - Ex-Post Assessments of Regulatory Impacts

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Tier 1 – Phase 1: GRP International Benchmark (continued)

- Central Regulatory Oversight Body

  - Structure
    - Located Close to Important Government Decision Makers
    - Given Formal Authority of Regulatory Oversight
    - Staffed with Experts and Given Independence
    - Given the Necessary Scope of Review to be Effective

  - Functions
    - Establish and Foster Good Regulatory Practices and Principles of Regulation
    - Ensure Forward Planning of Regulatory Activity
    - Review Proposed and Final Regulatory Measures before they are Published
    - Coordinate International Regulatory Cooperation

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Tier 1 – Phase 1: GRP International Benchmark (continued)

World Trade Organization – Technical Barriers to Trade Agreement

Article 2: Preparation, Adoption and Application of Technical Regulations by Central Government Bodies

2.4 Where technical regulations are required and relevant international standards exist or their completion is imminent, Members shall use them, or the relevant parts of them, as a basis for their technical regulations…

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Project Progress – Tier 2:

- Tier 2 – Phase 1: 100% Complete
  - MedTech GRP, TR, Standards, Conformity Assessment international benchmark
- Tier 2 – Phase 2: 100% Complete
  - Medtech Technical Regulation, Standards, Conformity Assessment GAP analysis
- Tier 2 – Phase 3: 100% Complete (initiation and buy in)
  - Bilateral cooperation (MD regulators, MOHs, NSBs, industry)
- Tier 2 – Phase 4: 98% Complete (initiation and buy in)
  - Multilateral cooperation (MD regulators, MOHs, NSB, industry)

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Tier 2 – Phase 1: Medtech GRP, TR, Standards, CA International Benchmark

1. WHO Global Model Regulatory Framework for Medical Devices Including IVD Medical Devices
2. Asia Harmonization Working Party (AHWP) Playbook for Implementation of Medical Device Regulatory Frameworks
3. International Medical Device Regulators Forum (IMDRF) documents (all), including:
   - IMDRF N47 - "Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices"
   - IMDRF N51 - Standards WG (PD1)/N51 "Optimizing Standards for Regulatory Use"
4. Global Harmonization Task Force (GHTF) Documents
5. ISO 16142-1: 2016 "Medical Device – Recognized essential principles of safety and performance of MDs – Part 1 (non-IVD)"
6. ISO 16142-2: 2017 "Medical Device – Recognized essential principles of safety and performance of MDs – Part 2 (IVD)"

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WHO Global Model Regulatory Framework for Medical Devices Including IVD Medical Devices

Chapter 4. Establishing a stepwise approach to regulating medical devices

This Model recommends establishing a regulatory system for medical devices taking a staged or stepwise approach – from basic to expanded controls. The regulatory framework must be sustainable, expandable and accommodate advances in clinical practices, public health needs and evolving technologies. The basic controls will form the foundation for the expanded controls. In order to promote international regulatory convergence and harmonization, this Model encourages countries to adopt the principles recommended in internationally harmonized technical guidance into their legislation.

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Project Accomplishments:

Institutional Awareness and Cooperation:

- LatAm Medtech Associations, Standards Bodies and SDOs
- Presidencies, Agencies of Central Regulatory Review, Trade Ministries
- MedTech Regulators and Ministries of Health
- Pan American Health Organization (PAHO)
- Inter-American Development Bank (IDB)
  - Americas Business Dialogue (ABD)
  - Summit of the Americas
- APEC aligned for LatAm economies (Chile, Mexico, Peru)
- Brazil - Government and Industry

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Project Accomplishments:

GRP/RIA Implementation

- Colombia, Mexico (Argentina, Brazil, Chile, Peru)

MD GRP Implementation & IMDRF

- Colombia, Mexico (Argentina, Brazil)

MD Regulator – Industry – Standards Cooperation

- Colombia, Costa Rica, Mexico, Peru, (Brazil)

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Standards Alliance – PAHO – LatAm MD Regulatory Workshop
Sep 19, 2017 – Ottawa, Canada

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Standards Alliance – PAHO – LatAm MD Regulatory Workshop
Oct 23, 2018 – San Salvador, El Salvador

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Key Project Findings:

- Ministries of Health and MD Regulatory Agencies:
  - Now aware of Intl Medical Device Regulatory Benchmarks:
    - WHO, IMDRF, AHWP, PAHO, ISO/IEC/AAMI/ASTM/CLSI, etc.
    - Recommendations on Reliance and Stepwise Approach
  - Have not published formal policies to implement

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Key Project Findings:

- WTO/TBT commitments clear with:
  - Ministries of Trade, Central Regulatory Oversight Bodies, Inter-Ministerial Committees, TBT points of contact within Ministries of Trade and Medical Device Regulatory Agencies

- WTO/TBT commitments not systematically implemented with:
  - Ministries of Health and MD Regulatory Agency teams that develop regulations:
    - Agency-level policies lacking that require:
      - Search for relevant international standards and CA as a pre-step to drafting regulation
      - Agency use of relevant international standards
      - Agency participation in (international) standardization
      - Agency RIA / ex-post review of international standards and CA use
      - Agency publication of standards and CA use
      - Designated positions charged with the responsibilities above

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Standards Alliance – INVIMA Delegation
Jan 19, 2018 – Washington, DC

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Next Steps:

- Tier 1 & Tier 2 Webinars / GAP Analyses Roll Outs (Q4 2018)
- Final Report Submission

Continuing Private Sector Support

- Scheduling of 2018-2020 Capacity Building Meetings
  - Regional: IDB, APEC, PAHO, AHWP
  - Colombia: ICONTEC, ANDI-CDMIS, INVIMA, MOH
  - Costa Rica: INTECO, COGR
  - Mexico: DGN/ANCE, AMID, COFEPRIS, MOH
  - Peru: INACAL, CCL, DIGEMID, MOH
  - (+ Argentina, Chile et al)

AdvaMed Global Priorities

Improve Patient Access to Care

- Health System Management
- Value Based Care
- Health Technology Assessments
- GRPs and International Standards
  - Procurement/Tendering

Health Perspectives

Standards Alliance

https://standardsalliance.ansi.org/Project-for-the-Medical-Device-Sector.aspx

Live Changing Innovation

https://www.lifechanginginnovation.org

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