AdvaMed Latin America Regional Priorities - by Thematic Area

				
Priorities	Minimizing Heath Market Bottlenecks, Barriers and Inefficiencies	Increasing the use of International Regulatory Best Practices	Strengthening Ethical Business Practices	Improving Patient Access to Care and Innovative Care Management
Also Known As	Trade Facilitation Market Access Administrative Efficiency	Regulatory Coherence and Convergence	Ethics & Compliance	Health Care Access
Task 1	Conduct Heath Market Logistics Benchmarking to identify and measure economic waste in the health system	Implement whole-of-government Regulatory Coherence policies including Regulatory Impact Assessment (RIA), Transparency, and Central Regulatory Review (CRR)	Take leadership role in the development, adoption, and implementation of high-standard ethical industry practices	Improve health system management
Task 2	Bring product approval and facility inspection times within legal limits and international norms	Engage in bilateral, regional and international regulatory cooperation and harmonization	Strengthen and harmonize industry codes of ethics through an Inter-American Coalition	Modernize public procurement policies
Task 3	Bring product customs clearance times within legal limits and international norms	Leverage international standards and conformity assessment tools to improve the quality of public administration	Measure and maximize adherence to codes and strengthen alignment of practices with non-industry stakeholders	Ensure Health Technology Assessment (HTA) is utilized in a transparent, fair manner that promotes access to care and quality healthcare

Detailed List of Current and Continuing Actions/Activities – per Thematic Area

	
Priorities	**Minimizing Heath Market Bottlenecks, Barriers and Inefficiencies**
Also Known As	**Trade Facilitation** **Market Access** **Administrative Efficiency**
Task 1	**Conduct Heath Market Logistics Benchmarking to identify and measure economic waste in the health system** • 2018: Support ABIIS/ABIMED study on breakdown of Brazilian healthcare cost inflation and causes • 2018: Support ABIIS/ABIMED updated study on impact of non-renewal of medical product tax exemption expiring Oct 2018
Task 2	**Bring product approval and facility inspection times within legal limits and international norms** • 2017: Formal submission of issues into ANVISA and INMETRO regulatory agendas • 2017: Multiple AdvaMed/ABIIS/ABIMED/CBDL meetings with ANVISA, MOH, Embassy • 2017: Lodging of detailed input into the US-Brazil Commercial Dialogue with DOC/ITA and MDIC/SECEX and also with FDA • 2018: Continue/Deepen
Task 3	**Bring product customs clearance times within legal limits and international norms** • 2017: Raised visibility of ABIIS/ABRAIDI port delay economic impact • 2017: Formal submission of issues into ANVISA and regulatory agendas • 2017: Multiple AdvaMed/ABIIS/ABIMED/CBDL meetings with ANVISA, MOH, Casa Civil, Congress, Foreign Ministry, Embassy • 2017: Lodging of detailed input into the US-Brazil Commercial Dialogue with DOC/ITA and MDIC/SECEX and also with FDA • 2018: Continue/Deepen

	
Priorities	**Increasing the use of International Regulatory Best Practices**
Also Known As	**Regulatory Coherence and Convergence**

Task 1	**Implement whole-of-government Regulatory Coherence policies including Regulatory Impact Assessment (RIA), Transparency, and Central Regulatory Review (CRR)**
	• 2017: Implement USAID/ANSI/AdvaMed Standards Alliance Project:
	  ○ Tier 1: Regulatory Coherence:
	  ▪ Identification/Consolidation of international benchmarks
	  ▪ GAP analysis for Colombia, Mexico, Peru, Costa Rica
	  ▪ Bilateral meetings with Casa Civil, COFEMER, and Colombian, Peruvian and Costa Rican equivalents
	• 2017: Presentation to Brazilian Inter-Ministerial Trade Chamber (CAMEX) and formal comments submission to public consultation
	• 2017: Formal endorsement by U.S. Chamber of Commerce, Association of American Chamber of Commerce in Latin America (AACCLA), Americas Business Dialogue (ABD) and members, ABD Secretariat – the Inter-American Development Bank (IDB)
	• 2018: Formal endorsement by Summit of the Americas Leader and CEOs in Lima
	• 2018: Continue/Deepen

Task 2 and
 	
Task 3
	Engage in bilateral, regional and international regulatory cooperation and harmonization
	
	Leverage international standards and conformity assessment tools to improve the quality of public administration
	• 2017: Implement USAID/ANSI/AdvaMed Standards Alliance Project:
	  ○ Tier 2: Medical Device GRP, Model Regulatory Frameworks, IMDRF Documents, International Standards and Conformity Assessment Policy, Dev. and Use:
	  ▪ Identification/Consolidation of international benchmarks
	  ▪ GAP analysis for all LatAm
	  ▪ Bilateral meetings with ANVISA, COFEPRIS, INVIMA
	• 2017: Support AMID for COFEPRIS Workshops
	• 2017: Support ANDI-CDMIS for INVIMA/GMDA study
	• 2017: Secure formal PAHO endorsement of AdvaMed/ALDIMED/ALADDIV initiatives and Standards Alliance Project
	• 2017: PAHO IMDRF Workshop for LatAm MD regulators
	• 2018: Continue/Deepen

	
Priorities	**Strengthening Ethical Business Practices**
Also Known As	**Ethics & Compliance**
Task 1	**Take leadership role in the development, adoption, and implementation of high-standard ethical industry practices** • 2017: Support establishment of global GMTA code of ethics and principles based on AdvaMed code • 2017: Provide US speaker to ABIMED/Hospitalar panel on US Sunshine Act • 2017/2018: Develop video webinar on US Sunshine Act • 2018: Continue/Deepen
Task 2	**Strengthen and harmonize industry codes of ethics through an Inter-American Coalition** • 2017: Establish Inter-American Coalition of Business Ethics for the Medical Device Sector, Action Plan, Bogotá Principles • 2017: Support AMID re APEC MD/SME compliance • 2017: Support ALDIMED and ALADDIV re regional compliance • 2017/2018: Host coalition executive committee and plenary meetings • 2017/2018: Support ANDI-CDMIS and ASEDIM in revising their codes of ethics • 2018: Outreach to Central American distributer associations to establish codes of ethics and conduct distributer workshops • 2018: Continue/Deepen • 2019: Plan in conjunction with APEC in Chile
Task 3	**Measure and maximize adherence to codes and strengthen alignment of practices with non-industry stakeholders** • 2017: Support ABIIS / Health Ethics Institute to reduce backlog of cases under review • 2017/2018: Support ABIIS/ABIMED/CBDL/ABRAIDI multi-stakeholder ethics conference – April 10, São Paulo • 2018/2019: Working with the LatAm Compliance Committee, consider recommendations for 3rd-party auditing to association codes of ethics

	
Priorities	**Improving Patient Access to Care and Innovative Care Management**
Also Known As	**Health Care Access**
Task 1	**Improve health system management** • 2016/2017: Brazil: AxiaBio Bottleneck Study and Dialogue Consultation • 2016/2017: Brazil: CSA Analysis of proposed price control bills • 2016/2017: Brazil: Support ABIMED medtech complexity study • 2017/2018: Brazil: Improve understanding of Japanese reimbursement and other global models in preparation for GOB inquiries • 2018/2019: Support bilateral and multilateral efforts to capacity build MOH and regulator management qualifications, practices, and systems • 2018/2019: Mexico: Support AMID and partner efforts to overhaul/streamline/consolidate the Mexican health technology incorporation process
Task 2	**Modernize public procurement policies** • 2017: Support AdvaMed Global Reimbursement Studies and World Bank Procurement Initiative • 2017: Brazil: Follow USTDA initiative • 2018: Continue/Deepen
Task 3	**Ensure Health Technology Assessment (HTA) is utilized in a transparent, fair manner that promotes access to care and quality healthcare** • 2017: Support AdvaMed Global Reimbursement Studies and World Bank Procurement Initiative • 2017: Brazil: prevent passage of Healthcare Technology Incorporation Bill - PL 415/2015 without legal criteria • 2018: Continue/Deepen

Tier 1 - Brazil

Priority 1 – Strengthen Ethics and Compliance in the medical device sector

Work to align codes of ethics for the sector in Brazil with regional and global standards and demonstrably increase compliance with them.

Priority 2 – Mitigate Price Controls

Mitigate the implementation of price controls for medical products and devices

- Increase understanding of healthcare value and cost-benefit analyses in procurement purchases
- Increase understanding of the value of innovation
- Support public policies aimed at controlling healthcare costs vs prices
- Increase transparency and understanding of the causes of healthcare cost increases
- Increase understanding of different international models of medical device economic regulation and procurement globally

Priority 3 – Reduce Import Delays

Reduce the delay of importation of medical devices to the previous 3-5 day window

- Continue communication and cooperation with ANVISA and all related policymakers to increase the visibility of the impact of the import delays to the Brazilian health system and to implement systemic changes, including:
    - Implementation of increased risk assessment: Simplified procedures for low-risk (class I and II) medical devices
    - Modification of the ANVISA personnel rules which would allow relocation and assignment of PAF staff and resources to critically delayed ports
    - Implementation of an integrated and dynamic digital electronic system, eliminating all paper documents and allowing remote inspection of port documentation
    - Increasing emergency PAF funding and staffing to reduce the backlog until the average import times fall back within the 5-day window.

Priority 4 – Promote regulatory convergence between ANVISA, INMETRO and their international counterparts

Priority 5 – Reduce manufacturing facility inspection times and fees

Horizontal Priority 1: Reintegrate ABIMED into the ABIIS alliance

Horizontal Priority 2: Support and capacity build with ABIIS and associations

Tier 2 – Colombia

Priority 1 – Strengthen Ethics and Compliance in the medical device sector
Work to align codes of ethics for the sector in Colombia with regional and global standards and demonstrably increase compliance with them.

Priority 2 – Mitigate Further Price Controls
Mitigate further implementation of price controls for medical products and devices

- Increase understanding of healthcare value and cost-benefit analyses in procurement purchases
- Increase understanding of the value of innovation
- Support public policies aimed at controlling healthcare costs vs prices
- Increase transparency and understanding of the causes of healthcare cost increases
- Increase understanding of different international models of medical device economic regulation and procurement globally

Priority 3 – Promote regulatory convergence between INVIMA and its international counterparts. Work to get INVIMA accepted into the IMDRF.

Horizontal Priority 1: Support and capacity build with ANDI-CDMIS

Tier 2 – Mexico

Priority 1 – Strengthen Ethics and Compliance in the medical device sector
Work to align codes of ethics for the sector in Mexico with regional and global standards and demonstrably increase compliance with them.

Priority 2 – Streamline the Mexican Formulary System

- Reduce the time the National Formulary Board takes to make decisions to incorporate new technologies
- Increase the percentage of new healthcare technologies the National Formulary Board makes in its decisions
- Reduce the complexity of the National Formulary Board process to incorporate new healthcare technologies
- Eliminate the second tier in the Mexican health technology incorporation process by reducing, consolidating or otherwise standardizing the number of processes at the 2nd-tier.

Priority 3 – Promote regulatory convergence between COFEPRIS and its international counterparts. Work to get COFEPRIS accepted into the IMDRF.

Horizontal Priority 1: Support and capacity build with AMID

Tier 3 – Central America

Priority 1 – Strengthen Ethics and Compliance in the medical device sector
Work to establish and align codes of ethics for the sector in the region with regional and global standards and demonstrably increase compliance with them.

Priority 2 – Promote regulatory convergence between medical device regulators in the region and their international counterparts.

Regional

Priority 1 – Strengthen Ethics and Compliance in the medical device sector
Work to establish and align codes of ethics for the sector in the region with regional and global standards and demonstrably increase compliance with them.

- Maintain the support of the Inter-American Coalition of Business Ethics for the Medical Device Sector. Advance Action Plan. Approve Bogotá Principles.
- Support ALDIMED re Coalition
- Consider partnership with IDB/OECD

Priority 2 – Promote regulatory convergence between medical device regulators in the region and their international counterparts.

- Maintain and strengthen collaboration with PAHO
- Support ALADDIV re Standards Alliance

Horizontal Priority 1: Support and capacity build with ALDIMED and ALADDIV