MEDICAL TECHNOLOGY:

Bringing Innovation & Value to Healthcare Across Latin America

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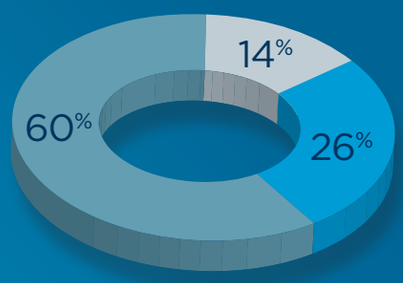
WHO WE ARE

The Advanced Medical Technology Association (AdvaMed) is the world's largest medical technology association, serving over 300 member companies who develop and manufacture products for every country in Latin America. AdvaMed works with partners around the world for the highest standards of ethics and integrity, timely access to safe and quality products, and national policies that encourage innovation and value creation through reasonable reimbursement. AdvaMed also supports regulatory environments that are transparent, predictable, consistent, timely and science-based, to expand patient access to advanced medical technologies. AdvaMed collaborates with national and local governments as well as industry associations, patient and civil society organizations, health care professionals and their colleges to support these objectives.

MEMBERSHIP BY COMPANY SIZE



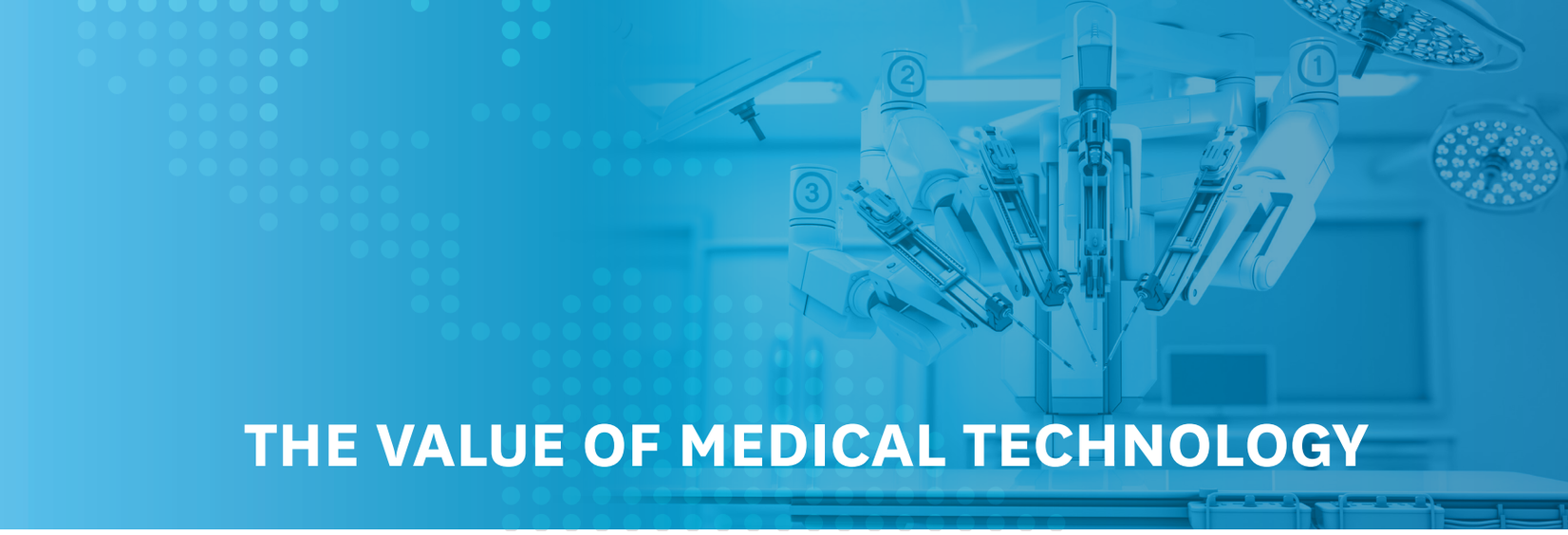
60% Emerging Growth Companies

14% Small to Midsize Companies

26% Large Companies

AdvaMed
Advanced Medical Technology Association

LATIN AMERICA



THE VALUE OF MEDICAL TECHNOLOGY

Medical technologies allow people to live longer, healthier and more productive lives. These life-changing innovations encompass more than 14,000 product categories, from bandages and surgical instruments to imaging devices and mobile phone applications. They are vital in the prevention, diagnosis, and treatment of health conditions and, therefore, fundamental to the quality of healthcare systems for patients, their families, and medical professionals.

In addition, medical technologies generate economic returns that are substantially greater than their costs, meaning that advanced medical devices and diagnostics not only bring immense benefit to individuals, but a brighter economic future for countries as a whole.[1] Some technologies increase direct health costs in the short term. However they drive long-term costs down by reducing the need for hospitalization, drugs or other treatments. And by allowing people to return to work sooner and preventing disability, they also raise GDP, increase personal income and generate additional tax revenue. Continued investment in medical devices and diagnostics, and policies that support enhanced investment for them, will generate larger net savings over time.

Health Savings from Medical Technology

Researchers from the Milken Institute examined insulin pumps used to diagnose and treat diabetes. What did they find?

While people using pumps face higher upfront costs than those who self-inject insulin, pump users visit emergency rooms less and are not as likely to experience the most expensive side effects of diabetes, like amputations, kidney failure or blindness. In the United States, each pump user saves the health care system $608. Furthermore, pump users participate in the workforce at higher rates and are more productive. Consequently, on average they contribute $5,278 more per person to the U.S. economy than do those who self-inject insulin.

DID YOU KNOW?

- Over the past 30 years, medical advancements have helped add five years to life expectancy in the United States and reduce fatalities from heart disease and stroke by more than 50 percent.[2]
- Between 1980 and 2010, advanced medical technologies have helped reduce the number of days people spent in hospitals by 59 percent.[3]

[1] To view the full study, visit: http://lifechanginginnovation.org/get-facts

[2] National Center for Health Statistics. "Health, United States, 2015" Hyattsville, MD. May 2016.

[3] National Center for Health Statistics. (2013, March 14). Table 103 – Discharges, days of care, and average length of stay in nonfederal short-stay hospitals, by selected characteristics: United States, selected years 1980 through 2009-2010. Retrieved March 15, 2013, from Centers for Disease Control and Prevention: http://www.cdc.gov/nchs/data/hus/2011/103.pdf.

Medical Technology vs Pharmaceuticals

A common misconception is that medical technology is the same as pharmaceuticals (drugs). This has led some countries to regulate medical technologies as drugs. However, as the table below highlights, the two are very different. The indiscriminate and arbitrary application of regulations for drugs to medical technologies threatens the development and quality of, and access to, medical technology. Moreover, the ambiguity of the regulatory framework can stunt the growth of the medical technology industry, thereby restricting patient access. Increasingly, countries are appreciating that medical technologies and pharmaceuticals are distinct and, therefore, require distinct regulatory frameworks.

	MEDICAL TECHNOLOGY	PHARMACEUTICALS (DRUGS)
		
DIVERSITY	Extremely diverse group of products with very diverse components. Wide variety of applications.	Single-molecule or specific compounds typically in the form of pills, solutions, aerosols, or ointments.
SCIENTIFIC DISCIPLINES	Active components based on mechanical, electrical, materials engineering. Some incorporate and/or are driven by software.	Based on pharmacology and chemistry, and increasingly encompass biotechnology and genetic engineering
PRODUCT DEVELOPMENT	Designed to perform specific functions and approved on basis of safety and efficacy.	Developed by discovery, trial, and approved on basis of safety and efficacy.
PATENT STRUCTURES	Due to the wide variety of structures and components embodied, many different patents cover a single medical technology. Thus, patents are not the basis for competition and do not confer market exclusivity. Short life cycle and investment recovery period with intense competition.	There are typically very few patents for individual pharmaceutical products. Therefore, patents form the basis of competition. Typically have a long commercial life-cycle of many years, during which they do not undergo significant changes
ROLE OF HEALTH CARE PROFESSIONALS	Training of health care professionals is critical so medical technologies are installed and/or used safely and properly. Many products are developed by doctors or nurses.	Health care professionals play a different and sometimes limited role. Many products are developed in laboratories by chemists and pharmacologists.
SUPPORT PROVIDED	In most cases, large investment in manufacturing, distribution, and training/education with need to provide ongoing services and maintenance.	In most cases, low manufacturing and distribution cost, little or no training, service or maintenance costs.

ADVAMED PRIORITIES FOR LATIN AMERICA

Medical technologies save and improve the lives of millions of people across Latin America every day, driving economic growth and workforce productivity. Rapidly growing demand for medical technologies across the region creates significant opportunities for foreign investment as well as locally driven growth, so long as policies and regulations that enable innovation and value creation are developed and implemented. AdvaMed serves as an advocate and partner across Latin America to maximize access to health care, pursuing lower costs to health systems while increasing the utilization of new medical technologies, through the following priorities:

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
TASK 2	Bring product approval and facility inspection times within legal limits and international norms
TASK 3	Bring product customs clearance times within legal limits and international norms

Increasing the use of International Regulatory Best Practices	Strengthening Ethical Business Practices	Improving Patient Access to Care and Innovative Care Management
Regulatory Coherence and Convergence	Ethics & Compliance	Health Care Access
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
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
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 transparent, fair manner that promotes access to care and quality healthcare

ADVANCING TRADE FACILITATION

Significant barriers at national borders, including unnecessary procedures on the release and clearance of medical technologies, prevent medical technology products from reaching the people who need them. Overly complex trade processes and documentation not only cause life-threatening delays but also raise costs, especially for the small and medium-sized businesses and entrepreneurs who own and operate the majority of medical technology companies.

More transparent and predictable border procedures make it easier for small and medium-sized businesses and entrepreneurs to connect with customers for the first time. And countries where medical technology goods can be imported or exported within quick and reliable timeframes are attractive for new or expanded investments.

AdvaMed is committed to working with its partners to enhance the movement of medical technologies across borders. This includes fast and efficient customs and port procedures. Therefore, AdvaMed supports widespread implementation of the ratified WTO Trade Facilitation Agreement (TFA). A recent WTO study suggests that implementing TFA reforms could create more than 20 million jobs worldwide, particularly in Latin America's emerging countries.

AdvaMed welcomes working with partners to implement country-specific reforms, such as those recommended by the Organization for Economic Co-operation and Development (OECD)[4] and the World Economic Forum *Enabling Trade Report*.[5]

[4] **http://www2.compareyourcountry.org/trade-facilitation**

[5] **http://reports.weforum.org/global-enabling-trade-report-2016/economy-profiles/**

HOW DO LATIN AMERICAN COUNTRIES MEASURE UP ON TRADE FACILITATION?

			TIME TO EXPORT		TIME TO IMPORT	
	RANKING (out of 136)	SCORE (1-7 best)	BORDER COMPLIANCE (hours)	DOCUMENTARY COMPLIANCE (hours)	BORDER COMPLIANCE (hours)	DOCUMENTARY COMPLIANCE (hours)
ARGENTINA	94	4.0	21	30	60	192
BOLIVIA	112	3.8	48	192	114	96
BRAZIL	110	3.8	49	18	63*	120
CHILE	21	5.3	60	24	54	36
COLOMBIA	85	4.1	112	60	112	64
COSTA RICA	57	4.5	20	24	80	26
DOM. REP.	78	4.2	16	10	24	14
EQUADOR	81	4.1	96	24	24	120
EL SALVADOR	74	4.3	38	9	40	13
GUATEMALA	69	4.3	36	48	72	32
HONDURAS	86	4.1	88	48	96	72
MEXICO	51	4.6	20	8	44	18
NICARAGUA	76	4.2	60	48	72	16
PANAMA	58	4.5	24	16	24	6
PARAGUAY	107	3.9	120	24	48	36
PERU	54	4.5	48	48	72	72
USA	22	5.2	2	2	2	8
URUGUAY	66	4.4	120	24	13	72
VENEZUELA	136	2.9	288	528	240	1,090
AVERAGE (LatAm)	76	4.2	64	56	121	101
AVERAGE (OECD)	22	5.2	12	3	9	4

Source: World Economic Forum 2016 Enabling Trade Index & the World Bank Doing Business Project (June 2016)

* AdvaMed Note: The World Bank index does not systematically include regulated medical products in its methodology; the AdvaMed/ABIIS/ABRAIDI corrected measurement of the border compliance import time of medical devices into Brazil is **360 hours.**

Case Study: Brazil

Companies report long timeframes to clear medical technology through air and seaport customs in Brazil, principally due to an increasingly critical bottleneck of the regulatory inspection procedures conducted by the ANVISA PAF division (ports, airports, borders). In 2016, these delays increased to over 60 days versus the previous 5-day average[6] at a cost to the Brazilian health system of USD 196,000,000 (BRL 660,000,000).[7] While Brazil has ratified the WTO Trade Facilitation Agreement (TFA), the Brazilian government TFA implementation timeline does not anticipate systematic relief of this issue until 2020. AdvaMed welcomes and supports efforts by ANVISA to address the bottlenecks through a combination of the following measures:

- 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; and
- Increasing emergency PAF funding and staffing to reduce the backlog until the average import times fall back within the 5-day window.

[6] www.abraidi.org.br
[7] http://www.abiis.org.br/assets/posicionamento-sobre-os-atrasos-na-liberação-de-insumos-e-produtos-sujeitos-à-vigilância-sanitária-em-portos%2c-aeroportos-e-fronteiras--05.07.16.pdf

PROMOTING REGULATORY COHERENCE & CONVERGENCE

A fundamental role of government is to protect and promote public health. This objective is enabled by a system of laws, regulations and guidelines. The degree to which the regulatory framework fulfils policy objectives depends on the quality of regulatory development and implementation. If done right, then governments can enable higher quality regulation, improved regulatory decision-making, increased efficiency of regulatory systems, and better public health outcomes – without unintended effects of restricting or distorting trade.

Regulatory and other non-tariff barriers are the hurdles that medical technology companies increasingly face. For example, regulatory changes implemented without adequate prior notification can severely restrict market access for companies and their products in a given country. Poorly developed regulations also create unnecessary trade barriers ("red tape"), as well as increasing costs for health systems and the public. Increasingly, governments around the world recognize that the highest cost-benefit regulations are those that maximize protection of public health, safety and the environment while simultaneously maximizing the impact of limited government resources. Implementation of the least economically restrictive public policies from a set of alternatives of the same efficacy minimizes costs to society by economizing the time and resources of every level of the healthcare supply chain, including those of governments, healthcare providers, hospitals, physicians, manufacturers, and patients.

AdvaMed welcomes partnering with governments and other stakeholders in Latin America to provide private sector resources and expertise to build capacity in "Regulatory Coherence" and "Regulatory Convergence" – policy tools that support the high quality, cost-effective, predicable, science-based and least economically restrictive regulations that are essential to fostering innovation and ensuring people have timely access to safe and effective medical technologies.

Regulatory Coherence and Good Regulatory Practices

Good Regulatory Practices (GRPs) are global best practices for making regulations. Per the Organization for Economic Co-operation and Development (OECD), "GRPs are internationally recognized processes, systems, tools and methods for improving the quality of regulations. GRP systematically implements public consultation and stakeholder engagement as well as impact analysis of government proposals, before they are implemented to make sure they are fit for purpose and will deliver what they are set out to achieve."[8] GRPs are "a la carte" policies and may be adopted "vertically" by sector specific regulators and/or "horizontally" by governments for use across multiple agencies.

"Regulatory Coherence", also known as "Good Regulatory Design" or "Regulatory Reform", is a horizontal, whole-of-government policy, managed at the top executive level of government, implementing the binding rules by which regulatory agencies generate regulations. Regulatory Coherence is the minimum package or set of GRPs that governments adopt horizontally across all of its agencies to ensure that the entire public administration of a country implements GRP in a consistent manner. Regulatory Coherence refers to the implementation and use of a comprehensive, consistent, transparent, and predictable set of GRPs in the process of planning, designing, issuing, implementing and reviewing regulatory measures in order to facilitate achievement of domestic policy objectives, and in efforts across governments to enhance regulatory cooperation in order to further those objectives and promote international trade and investment, economic growth and employment.

[8] http://www.oecd.org/gov/regulatory-policy/asean-oecd-good-regulatory-practice-conference-2015.htm

Several Regulatory Coherence and GRP tools have been developed:

THE 2005 APEC-OECD INTEGRATED CHECKLIST ON REGULATORY REFORM LAYS OUT A VOLUNTARY GRP FRAMEWORK FOR SELF-ASSESSMENT THAT INCLUDES REGULATORY POLICIES.

Necessary elements of Regulatory Coherence which comprise such policies include:

A) Transparency & Stakeholder Involvement
- Regulatory Forecast
- National Regulatory Register
- Notification and Public Comment
- Publication of Evidence/Regulatory Analysis
- Respond to Stakeholder Input
- Quality Data & Sound Science

B) Risk Based Approach
C) Regulatory Impact Assessment (RIA)
D) Pro-Competitive Analysis
E) International Impact
F) Use of International Standards
G) Ex-post Assessment
H) Central Regulatory Review, including establishment of a central regulatory oversight body

The 2017 Center for Global Regulatory Cooperation Good Regulatory Design document[9] is the first comprehensive compilation of global Regulatory Coherence principles and policies developed to serve as a guide for governments interested in better understanding and implementing fundamental whole-of-government regulatory coherence policies. The guide is written for senior policy makers at the highest level of government responsible for increasing the efficiency of the state and includes definitions of the key elements and a policy implementation checklist.

World Health Organization
REGIONAL OFFICE FOR THE Americas

The **World Health Organization (WHO) Good Regulatory Practices Guidelines for National Regulatory Authorities for Medical Products**, currently in draft form, seeks to: respond to requests from Member States for guidance on how to develop legal frameworks; serve as a foundational document that applies internationally accepted principles of GRP to the regulation of medical products; and apply to the establishment of new regulatory systems and the updating of existing ones.

Principles of GRP, according to the draft WHO Guidelines, include:

- Legality
- Impartiality
- Consistency
- Proportionality
- Flexibility
- Effectiveness
- Efficiency
- Clarity
- Transparency

Implementing GRP, according to the draft WHO Guidelines, includes:

- Conducting Regulatory Impact Analysis
- Compliance and enforcement (should be clear, proportionate and achievable)
- Consultation (at the center of an effective regulatory system)
- Forward looking regulatory agenda (identifies priorities in management of regulations)
- Monitoring and evaluation (verifying that regulatory intervention achieved its goal)
- Management of the regulatory stock (periodic review of all regulations to mitigate redundancies, inconsistencies and outdated instruments)

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

THE WORLD HEALTH ORGANIZATION (WHO) GLOBAL MODEL REGULATORY FRAMEWORK FOR MEDICAL DEVICES including IVD Medical Devices currently in draft form "is intended to provide guidance and support to WHO Member States that have yet to develop and implement regulatory controls relating to medical devices, as they take steps to ensure the quality and safety of medical devices available in their jurisdictions."

Key among the draft WHO Guidelines is the Chapter 4 "Stepwise approach in regulating medical devices" that, in recognition of the differing levels of development in which different countries may be, offers governments a prioritized layering of regulatory responsibilities that they can assume commensurate with their resources.

"The stepwise approach will allow the regulatory authority to respond to national public health priorities and to progressively develop the capacity, knowledge and experience required. This approach helps the regulatory authority determine the resources needed for further implementation. Without effective implementation of basic controls, the elements of expanded controls will be of limited value and difficult to manage effectively.

The regulatory authority has an opportunity to reduce the demands on its own staff by either relying upon or recognizing the work or decisions made by another medical devices regulatory authority."

The WHO stepwise approach thereby offers authorities a full range of regulatory tools to ensure the availability of safe and innovative medical technologies within a particular border, maximizing leverage of existing international regulatory systems and outputs. For countries particularly focused on economizing scarce public health resources, these guidelines can provide the requisite policy framework allowing the acceptance of foreign regulatory approvals in lieu of creating duplicative or conflicting regulatory regimes or requirements.

Regulatory Convergence

"Regulatory Convergence" represents a process whereby the regulatory requirements across countries or regions become more similar or aligned over time as a result of the gradual adoption of internationally recognized technical guidance documents, standards and scientific principles, common or similar practices and procedures, or adoption of regulatory mechanisms that might be specific to a local legal context but that align with shared principles to achieve a common public health goal. It does not necessarily represent the harmonization of laws and regulations, which is not a prerequisite for allowing the alignment of technical requirements and greater regulatory cooperation.

Several regulatory convergence initiatives exist for the medical device sector:

IMDRF International Medical Device Regulators Forum

INTERNATIONAL MEDICAL DEVICE REGULATORS FORUM (IMDRF) – Conceived in 2011, this forum discusses future directions in medical device regulatory harmonization. The IMDRF is a voluntary group of medical device regulators from around the world who come together to build on the foundational work of the Global Harmonization Task Force on Medical Devices (GHTF) and to accelerate international medical device regulatory harmonization and convergence. Brazil is currently the only Latin American full member country in the IMDRF. AdvaMed supports increasing the participation of Latin American medical device regulators in the IMDRF, by being invited as members or observers to facilitate an understanding and the adoption of recommended policies and standards.

Pan American Health Organization

PAN AMERICAN HEALTH ORGANIZATION (PAHO), PAN AMERICAN NETWORK ON DRUG [AND MEDICAL DEVICE] REGULATORY HARMONIZATION (PANDRH) – This network of health regulators from across the Americas region has begun examining medical device regulatory practices. AdvaMed supports the PANDRH role of facilitating Latin American medical device regulatory cooperation and harmonization in the medical device sector, particularly aligned with the IMDRF given PAHO's role as an IMDRF associate member.

The Pacific Alliance

CHILE COLOMBIA ECUADOR MEXICO PERU

THE PACIFIC ALLIANCE – Chile, Colombia, Ecuador, Mexico and Peru, as members of the Pacific Alliance, are advancing a Regulatory Coherence and Medical Device Regulatory Convergence Initiative. These efforts are augmented by the work of the *APEC Life Sciences Innovation Forum (LSIF), Regulatory Harmonization Steering Committee (RHSC)* which includes Chile, Mexico, and Peru. The RHSC promotes a coordinated approach to regulatory harmonization and capacity building efforts across the region.

Standards Alliance

STANDARDS ALLIANCE – An AdvaMed project has been approved by the U.S. Agency for International Development (USAID) and the American National Standards Institute (ANSI), to promote Regulatory Coherence, Good Regulatory Practices, and to provide capacity building and assistance under the Standards Alliance Initiative to several governments of developing countries in Latin America, including Colombia, Mexico, Peru and the CAFTA-DR[10] countries. The Standards Alliance Initiative is a funding facility designed to provide capacity-building assistance to developing countries, specifically related to implementation of the World Trade Organization (WTO) Technical Barriers to Trade (TBT) Agreement. The objective of AdvaMed's work is to provide private sector resources and expertise in support of international, regional, and national governmental initiatives in Latin America to adopt good regulatory practices in the medical technology sector. This aims to help governments maximize their regulatory efficacy through the adoption of international best practices, including the implementation and reinforcement of policies promoting the use of internationally harmonized voluntary consensus standards and conformity assessment mechanisms.

[10] Dominican Republic-Central America Free Trade Agreement (Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua, Dominican Republic).

Regulatory Harmonization Steering Committee

APEC

Life Sciences Innovation Forum

STRENGTHENING BUSINESS ETHICS & INTEGRITY

Ethical business practices and integrity are at the heart of healthcare by ensuring that decisions are made in the patients' best interests. They are also vital to sustainable growth for medical technologies across Latin America. Unethical business practices can result in public distrust of the health system, unfair business conditions or inaccessible market opportunities, wasted resources, stifled investment and innovation, a heightened enforcement burden, and non-harmonized practices between countries leading to elevated legal risks that reduce trade. At the same time, beneficial collaborations between medical technology companies and other stakeholders are also essential to enhance the safe and effective use of products, to encourage research and education, and to foster charitable causes. For these reasons, strengthening and aligning ethical business practices are a shared priority by all stakeholders in the health system – government, industry, health care professionals, and the public.

AdvaMed is a global leader in strengthening business ethics and integrity for the medical technology sector. The AdvaMed Code of Ethics on Interactions with Health Care Professionals ("AdvaMed Code") is a model for the industry and has been used as the basis for national medical technology sector codes of ethics in Brazil, Chile, Colombia, Mexico, Peru, and dozens of other countries in Latin America and around the world. These codes extend to thousands of companies. The AdvaMed Code also informed the *APEC Principles for Codes of Ethics in the Medical Device Sector* endorsed by APEC Leaders and Ministers and undergoing implementation by hundreds of organizations and their members across Latin America. AdvaMed also partners with governments, industry bodies, and health care professional groups across the region in ethics and integrity training programs, from in-person workshops to online resources. Since 2014, AdvaMed has partnered with major government and industry stakeholders to convene the Latin American Compliance Conference – the region's largest medical technology ethics program – held in São Paulo, Mexico City, Bogotá, and Miami.

AdvaMed supports partnerships in the Americas that are pioneering new approaches to strengthen business ethics and integrity. This includes best practice guidance for third party sales and marketing intermediaries, such as medical technology distributors, and implementing novel training for them in Brazil, Mexico, and Colombia. In 2016, AdvaMed joined with the U.S. Department of Commerce to aid in the launch of the Peruvian Consensus Framework. This ground-breaking agreement unites ethical business practices in the medical technology sector for Peru's 23 leading health stakeholders, including government authorities, industry associations, patient and civil society organizations, and health care professional groups.

Asia Pacific Economic Cooperation Forum

AdvaMed serves as the industry coordinator for the medical device sector program of the APEC Business Ethics for SMEs Initiative, one of the largest public-private partnerships in the world to strengthen ethical business practices.

The Inter-American Coalition on Ethical Practices in the Medical Technology Sector

The Inter-American Coalition on Ethical Practices in the Medical Technology Sector was launched during the February 2017 Latin American Compliance Conference, bringing together 15 national medical technology manufacturer and distributor associations under common terms to prepare a set of principles and a joint work plan that strengthens ethical business practices across the western hemisphere. With members to include government, health care professional and civil society organizations, the Coalition serves as the first public-private partnership spanning the entire region to strengthen ethical business practices in the medical technology sector.

Under AdvaMed's joint leadership with ANDI-CDMIS (Colombia) and CCL-COMSALUD (Peru), principals from medical technology enterprises and associations, governments, and other stakeholders from across the Americas gathered in Lima on 7 September 2016 to examine new opportunities for heightened regional collaboration in strengthening ethical business practices. The roundtable unanimously recommended the establishment of an Inter-American Coalition on Ethical Practices in the Medical Technology Sector, bringing together all relevant stakeholders under a common set of principles and a joint work plan through 2020.

HEALTHCARE ACCESS

Improving Patient Access to Care and & Innovative Care Management

Improving patient access to care and AdvaMed's members' lifesaving innovations are central to AdvaMed's mission. Included in lifesaving innovation are technologies that redesign or in some cases redefine the care pathway to improve efficiency, access and outcomes. AdvaMed advocates on behalf of its members in numerous markets to ensure patients have access to medical technology that is the most appropriate and effective.

AdvaMed also works with partner organizations to educate policymakers on how to advance the benefits of medical technology through public policies that support investment, innovation and patient access. One example is AdvaMed's work through the Medical Technology Group (MTG) in the UK. MTG is a collaboration between AdvaMed, the Association of British Healthcare Industries (ABHI) and patient groups on issues affecting patient access. MTG advocacy campaigns include "Admissions of Failure – The Truth About Unplanned Admissions in the NHS," which highlighted the need to better manage chronic conditions to avoid emergency room visits, and a campaign designed to highlight and combat patient lotteries for hip and knee surgery. MTG has also authored a report on the economic value of medical technology. The report, done in conjunction with the Work Foundation, highlights the often overlooked societal and economic benefit that medical technology plays in returning people to good health as quickly as possible. More information on MTG is available at **www.mtg.org.uk**. AdvaMed also collaborates in Germany with BVMed (the German medical technology trade association) on key issues. In India, AdvaMed has launched a social media campaign to highlight the diverse spectrum of medical technologies in the country that benefit patients' lives. The platform also informs stakeholders about important differences between medical devices and pharmaceuticals, to help drive home the need for device-specific policies and regulations.

Such partnerships help amplify AdvaMed's message on the importance of access to innovative new treatments and cures, and focus attention on the many disease states that can be addressed or alleviated through medical technology. In combination with these efforts, members are able to discuss with policymakers ways to ensure innovative technology and improvements in clinical management are given full consideration to make care more efficient and effective.

Modernize Public Procurement Policies

Public procurement can have an enormous impact on patient access to medical technology, particularly in emerging markets that may rely exclusively on direct procurement models. A number of global markets are increasingly focused on reducing reimbursement as a means to address budgetary issues. Such mechanisms appear to be more frequently utilized in markets where access to care is increasing the most rapidly. In many instances, an excessive focus on up-front costs has led to imposition of price controls, which fail to consider the full value medical technology brings to patients, the health care system and the economy over time. For example, advancements in medical technology often yield savings across the health care system by replacing more invasive procedures, reducing hospital stays, and allowing people to return to work more quickly. AdvaMed has convened several international forums over the last few years to develop consensus best practices for value-based procurement. These principles were formulated through collaborative efforts with thought leaders including physicians, hospitals, government entities as well as industry. Related White Papers can be viewed on AdvaMed's website.[11]

AdvaMed has also played a key role in working with the World Bank to develop a value-based procurement framework for medical technology. While the Bank's initial emphasis is primarily on capital equipment, AdvaMed's work with the Bank has resulted in adoption of broad value-based concepts that are applicable to situations in which governments want to obtain better value. The initiative is anticipated to conclude in 2017.

Ensure that Health Technology Assessments (HTAs) are transparent and fair, to promote access to quality care

AdvaMed has formulated principles on health technology assessment that help to define its appropriate role and utilization. AdvaMed works with local association partners to address unfairness in HTA processes. Not infrequently, HTAs are used as a barrier to market entry or as a mechanism to control costs, rather than as an attempt to assess value. AdvaMed has been on the forefront in many markets of holding HTA agencies accountable to ensure transparency and fairness, and to ensure appropriate data are accepted.

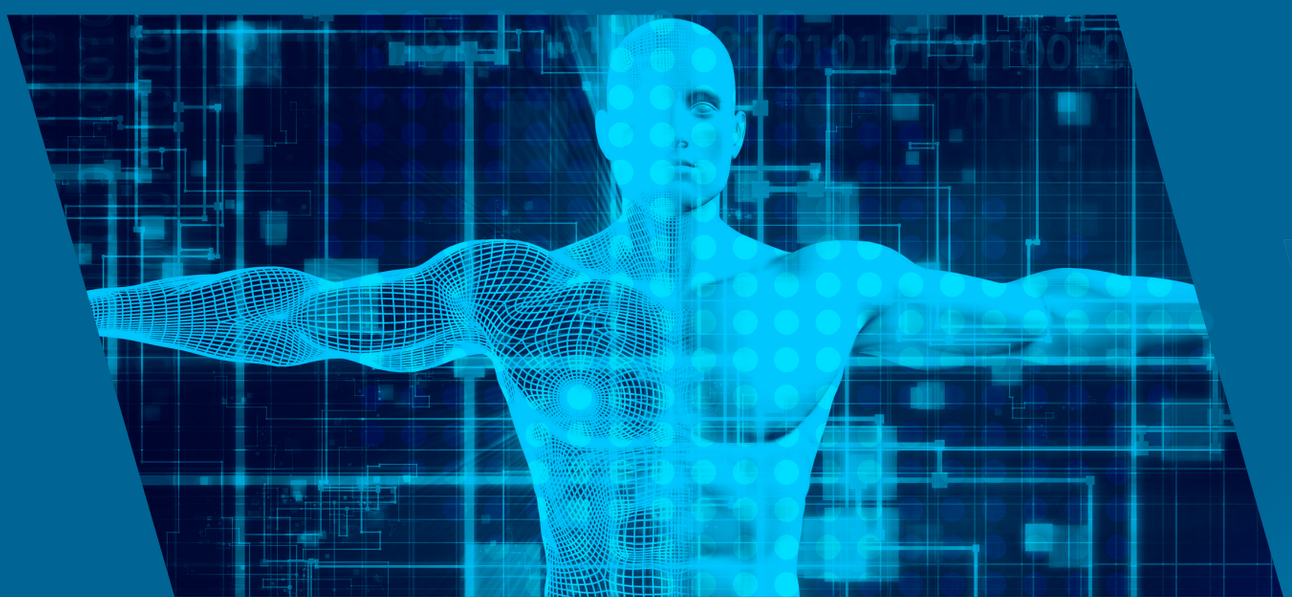
In some cases, AdvaMed has worked to ensure broader adoption of beneficial technologies with positive assessments. AdvaMed did this in the UK with insulin pumps. In Korea, AdvaMed has been successful in obtaining improvements in reviews that allow for greater reimbursement levels for innovative technology. In Germany, AdvaMed worked with a BVMed coalition to defeat a proposal that would have required benefit assessment studies for all Class IIB and III devices coming onto the market. In every market around the world, AdvaMed works to ensure that HTAs are transparent, fair and reflect the latest scientific knowledge.

[11] https://www.advamed.org/resource-center/good-practices-procurement-innovative-medical-technology

OUR COLLABORATIONS AND PARTNERS

As the world's largest medical technology association, AdvaMed prioritizes collaboration with leading health system stakeholders across Latin America. These local and regional partnerships with government and non-government organizations propel access to life saving and life changing products as well as ensure consistent dialogue on common challenges. Such partnerships are advanced through memorandums of understanding as well as through national or regional collective actions. AdvaMed's network of collaborations with leading industry associations across Latin America include:

ARGENTINA	CADIEM	Asociación Argentina de Distribuidores e Importadores de Equipos Médicos	Argentine Medical Equipment Importers and Distributors Association
	CADIME	Cámara de Instituciones de Diagnóstico Médico	Argentine Chamber of Medical Diagnostic Institutions
BRAZIL	ABIIS	Aliança Brasileira da Indústria Inovadora em Saúde	Brazilian Innovative Health Industry Alliance
	ABIMED	Associação Brasileira da Indústria de Alta Tecnologia de Produtos para Saúde	Brazilian High-Technology Health Products Industry Association
	ABIMO	Associação Brasileira da Indústria de Artigos e Equipamentos Médicos, Odontológicos, Hospitalares e de Laboratórios	Brazilian Medical, Orthodontic, Hospital and Laboratory Equipment and Product Industry Association
	ABRAIDI	Associação Brasileira de Importadores e Distribuidores de Implantes	Brazilian Implant Importers and Distributers Association
	CBDL	Câmara Brasileira de Diagnóstico Laboratorial	Brazilian In-Vitro Diagnostics Chamber
	IES	Instituto Ética Saúde	Brazilian Health Ethics Institute
CANADA	MEDEC	Empresas de Dispositivos Médicos de Canadá	Canada's Medical Device Companies
CHILE	SCDM	Sociedad Científica de Dispositivos Médicos	Chilean Scientific Society of Medical Devices
COLOMBIA	ANDI-CDMIS	Asociación Nacional de Empresarios de Colombia – Camera de Dispositivos Médicos	Colombian National Business Association – Medical Device Chamber
ECUADOR	ASEDIM	Asociación Ecuatoriana de Distribuidores e Importadores de Productos Médicos	Ecuadorian Medical Product Importers and Distributers Association
MEXICO	AMID	Asociación Mexicana de Industrias Innovadora de Dispositivos Médicos	Mexican Association of the Innovative Medical Device Industry
PERU	CCL-COMSALUD	Cámara de Comercio de Lima - Gremio de Salud	Lima Chamber of Commerce – Health Guild
VENEZUELA	AVEDIM	Asociación Venezolana de Distribuidores de Equipos Médicos, Odontológicos, de Laboratorios y Afines	Venezuelan Medical, Orthodontic and Laboratory Equipment and Product Distributors Association
REGIONAL	ALDIMED	Asociación Latinoamericana de Gremios de Dispositivos e Insumos Médicos	Latin American Alliance of Medical Device Associations
	ALADDIV	Asociación Latinoamericana de Diagnostico In-Vitro	Latin American Alliance for the Development of In-Vitro Diagnostics
	The Coalition	Coalición Inter-Americana de Ética Empresarial para el Sector de Tecnología Medica	Inter-American Coalition on Ethical Practices in the Medical Technology Sector



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