



**AdvaMed**  
Advanced Medical Technology Association

MEDICAL TECHNOLOGY:  
**Bringing Innovation & Value to  
Health Care Across Latin America**



LATIN AMERICA



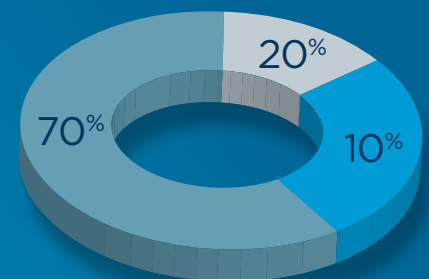
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## WHO WE ARE

The Advanced Medical Technology Association (AdvaMed) is the world's largest medical technology trade association. Headquartered in Washington, D.C., AdvaMed has a global presence — including Latin America, China, India, Japan and Europe — and over 400 global member companies that manufacture innovative, life-changing medical devices and diagnostics. 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 appropriate reimbursement. AdvaMed also supports regulatory environments that are transparent, predictable, consistent, timely and science-based, to advance universal health for all people. 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



- 70%** Emerging Growth Companies
- 20%** Small to Midsize Companies
- 10%** Large Companies

# 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 health care 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.<sup>1</sup> 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, will generate larger net savings over time.



## DID YOU KNOW? <sup>2,3</sup>

- 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 60 percent.
- Between 1980 and 2010, advanced medical technologies have helped reduce the number of days people spent in hospitals by 59 percent.

## Health Savings from Medical Technology



**Researchers from the Milken Institute examined insulin pumps used to diagnose and treat diabetes. What did they find? <sup>1</sup>**

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, the use of insulin pumps by diabetes patients generates annual savings of \$5,886 per person.

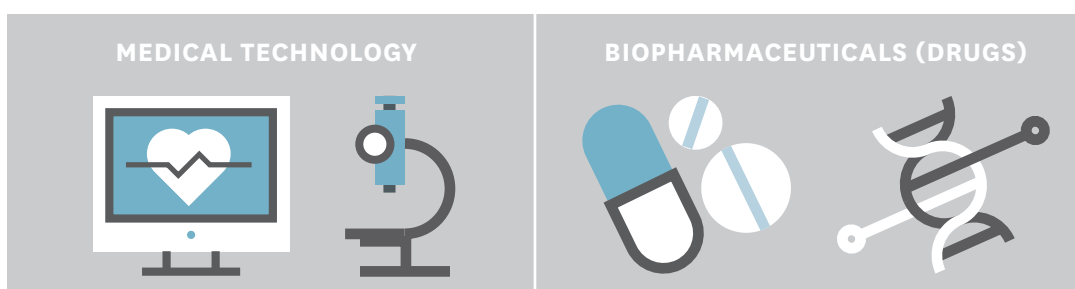
<sup>1</sup>To view the full study, visit: [https://www.lifechanginginnovation.org/sites/www.lifechanginginnovation.org/files/files/HealthySavingsFinal\(1\).pdf](https://www.lifechanginginnovation.org/sites/www.lifechanginginnovation.org/files/files/HealthySavingsFinal(1).pdf)

<sup>2</sup>National Center for Health Statistics. "Health, United States, 2018." Hyattsville, MD, October 2019.

<sup>3</sup>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/hsu/2011/103.pdf>.

## Medical Technology vs Biopharmaceuticals

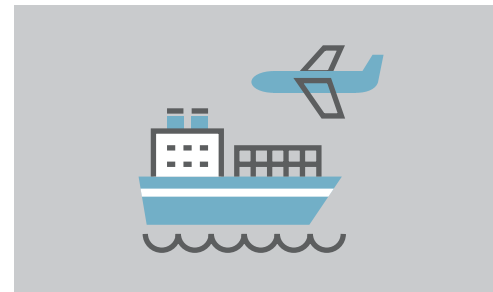
A common misconception is that medical technology is the same as biopharmaceuticals (drugs). This has led some countries to regulate medical technologies as drugs. However, as the table below highlights, the two are very different. The indiscriminate and arbitrary application of regulations for drugs 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 biopharmaceuticals are distinct and, therefore, require distinct regulatory frameworks.



|                                   | MEDICAL TECHNOLOGY   | BIOPHARMACEUTICALS (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 biopharmaceutical 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 PRIORITY AREAS 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:



|                      |  |
|----------------------|--|
| <b>PRIORITIES</b>    | Minimizing Medical Device Market Bottlenecks, Barriers and Inefficiencies  |
| <b>ALSO KNOWN AS</b> | Trade Facilitation<br>Market Access<br>Administrative Efficiency   |
| <b>TASK 1</b>        | Conduct medical device market logistics benchmarking to identify, measure and reduce economic waste in the health system |
| <b>TASK 2</b>        | Bring product approval and facility inspection times within legal limits and international norms                         |
| <b>TASK 3</b>        | Bring product customs clearance times within legal limits and international norms  |





Implementing International Regulatory Best Practices

Driving a Level Playing Field in Ethical Business Conduct

Improving Patient Access to Care and Innovative Care Management

Good Regulatory Practices (GRP) and Medical Device Regulatory Convergence

Ethics & Compliance

Health Care Access, Payment, Reimbursement

Implement whole-of-government GRP policies including Regulatory Impact Assessment (RIA), Transparency, Central Regulatory Review, et al.

Take leadership role in the harmonization and implementation of high-standard ethical industry practices

Improve health system management and goal prioritization

Engage in bilateral, regional and international regulatory cooperation and harmonization

Strengthen alignment of practices with third party intermediaries and non-industry stakeholders, including healthcare professionals

Modernize public procurement policies to international benchmarks

Leverage international standards and conformity assessment tools to improve the quality of public administration

Engage with governments to identify and pursue strategies that encourage ethical business conduct

Ensure that value-based care and procurement practices are transparent, fair, and promote patient access to quality care



# 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)<sup>4</sup> and the World Economic Forum *Enabling Trade Report*.<sup>5</sup>



<sup>4</sup> <https://www.compareyourcountry.org/trade-facilitation>



<sup>5</sup> <https://www.doingbusiness.org/en/data/exploretopics/trading-across-borders>

# HOW DO LATIN AMERICAN COUNTRIES MEASURE UP ON TRADE FACILITATION?

|                        | RANKING<br>(out of 190) | SCORE<br>(1-100 best) | TIME TO EXPORT                  |                                      | TIME TO IMPORT                  |                                      |
|------------------------|-------------------------|-----------------------|---------------------------------|--------------------------------------|---------------------------------|--------------------------------------|
|                        |                         |                       | BORDER<br>COMPLIANCE<br>(hours) | DOCUMENTARY<br>COMPLIANCE<br>(hours) | BORDER<br>COMPLIANCE<br>(hours) | DOCUMENTARY<br>COMPLIANCE<br>(hours) |
| <b>ARGENTINA</b>       | 119                     | 67.1                  | 21                              | 25                                   | 60                              | 192                                  |
| <b>BOLIVIA</b>         | 100                     | 71.6                  | 48                              | 144                                  | 114                             | 96                                   |
| <b>BRAZIL</b>          | 108                     | 69.9                  | 49                              | 12                                   | 30                              | 120                                  |
| <b>CHILE</b>           | 73                      | 80.6                  | 60                              | 24                                   | 54                              | 36                                   |
| <b>COLOMBIA</b>        | 133                     | 62.7                  | 112                             | 48                                   | 112                             | 64                                   |
| <b>COSTA RICA</b>      | 80                      | 77.6                  | 20                              | 24                                   | 80                              | 26                                   |
| <b>DOM. REP.</b>       | 66                      | 83.5                  | 16                              | 10                                   | 24                              | 14                                   |
| <b>ECUADOR</b>         | 103                     | 71.2                  | 96                              | 24                                   | 24                              | 120                                  |
| <b>EL SALVADOR</b>     | 46                      | 89.8                  | 24                              | 9                                    | 36                              | 13                                   |
| <b>GUATEMALA</b>       | 82                      | 77.2                  | 36                              | 48                                   | 72                              | 32                                   |
| <b>HONDURAS</b>        | 130                     | 64.3                  | 108                             | 48                                   | 96                              | 72                                   |
| <b>MEXICO</b>          | 69                      | 82.1                  | 20                              | 8                                    | 44                              | 18                                   |
| <b>NICARAGUA</b>       | 84                      | 77.0                  | 72                              | 48                                   | 72                              | 16                                   |
| <b>PANAMA</b>          | 59                      | 85.5                  | 24                              | 6                                    | 24                              | 6                                    |
| <b>PARAGUAY</b>        | 128                     | 65.1                  | 120                             | 24                                   | 24                              | 36                                   |
| <b>PERU</b>            | 102                     | 71.3                  | 48                              | 24                                   | 72                              | 72                                   |
| <b>USA</b>             | 39                      | 92.0                  | 2                               | 2                                    | 2                               | 8                                    |
| <b>URUGUAY</b>         | 150                     | 58.4                  | 96                              | 24                                   | 6                               | 72                                   |
| <b>VENEZUELA</b>       | 188                     | 0.0                   | N/A                             | N/A                                  | N/A                             | N/A                                  |
| <b>AVERAGE (LatAm)</b> | 106                     | 69.1                  | 55.3                            | 35.7                                 | 55.6                            | 43.2                                 |
| <b>AVERAGE (OECD)</b>  | 26                      | 94.3                  | 12.7                            | 2.3                                  | 8.5                             | 3.4                                  |

Source: The World Bank Doing Business Project (May 2019)

## Case Study: Brazil

Between 2016 and 2018, companies reported long timeframes to clear medical technology through air and seaport customs in Brazil, principally due to a critical bottleneck of the regulatory inspection procedures conducted by the ANVISA PAF division (ports, airports, borders). During this period, these delays rose to a peak of 60 business days versus the previous 5-day average<sup>6</sup> at a cost to the Brazilian health system of USD 196,000,000 (BRL 660,000,000).<sup>7</sup> AdvaMed worked in concert with its Brazilian MedTech Alliance partners in ABIMED, CBDL and ABRAIDI and the Brazilian government to address this critical bottleneck. In addition to its work to implement the WTO Trade Facilitation Agreement (TFA), ANVISA subsequently implemented the following measures which eliminated the delays with many goods now being cleared prior to arriving at port:



- Implementation of a new color coded risk assessment methodology aligned with the federal tax service: Simplified procedures for low-risk (class I and II) medical devices;
- 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.

This constituted a significant success story for ANVISA, the Brazilian medical technology supply chain, health system, and patients. AdvaMed's partners continue to monitor Brazilian medtech import times, supporting ANVISA with its policy to shift regulatory focus to post-market surveillance.

<sup>6</sup> [www.abraidi.com.br](http://www.abraidi.com.br)

<sup>7</sup> <https://abiis.org.br/abiis-posicionamentos-aprimoramento-institucional/>





# PROMOTING MEDICAL DEVICE REGULATORY CONVERGENCE AND GOOD REGULATORY PRACTICES

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 health care supply chain, including that of governments, health care providers, hospitals, physicians, manufacturers, and patients.

AdvaMed partners with governments and other stakeholders in Latin America to provide private sector resources and expertise to build capacity in Medical Device Regulatory Convergence and foundational Good Regulatory Practices (GRP) – policy tools that support the high quality, cost-effective, predictable, 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.

**Medical Device Sector Regulatory Convergence** is a concerted public-private effort to systematically pursue and maximize alignment of medical device sector-specific technical regulations, standards and conformity assessment criteria to harmonized international standards.<sup>8</sup>

**Good Regulatory Practices (GRP)** refers to a formalized, mandatory, whole-of-government policy, that defines the common and transparent rules by which regulatory agencies develop technical regulations for all regulated sectors (i.e., cross-sector, transverse, horizontal, foundational) following international standards for GRP. GRP is the quality control mechanism for the development of regulations, ensuring on a continuous and systematic basis that government rules are relevant, of the highest quality, cost-effective, internationally aligned and least economically restrictive amongst alternatives of the same purpose.



The Center for Global Regulatory Cooperation has developed a comprehensive compilation

of global Good Regulatory Practice principles and policies to serve as a guide for governments interested in better understanding and implementing fundamental whole-of-government GRP policies.<sup>9</sup> 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.

<sup>8</sup> The WHO provides a more detailed definition of regulatory convergence at: <https://www.interamericoalition-medtech.org/regulatory-convergence/policy/medical-device-sector-regulatory-convergence/world-health-organization-documents/>. Important is compatibility with this WHO guidance definition as well as with the international treaty obligations as defined in the WTO TBT agreement, particularly the article 2.4 requirement for WTO members to base national regulations on international standards.

<sup>9</sup> <https://www.interamericoalition-medtech.org/regulatory-convergence/projects/standards-alliance/>



The **INTER-AMERICAN COALITION FOR REGULATORY CONVERGENCE FOR THE MEDICAL TECHNOLOGY SECTOR** was launched in 2020 with a mission of regional regulatory cooperation toward the goal of internationally aligned medical device regulations, standards, and conformity assessment requirements within a continual process of convergence. The Coalition is comprised of and organized by the medical technology industry associations of the Americas and welcomes the participation, contributions from, and engagement with all affected stakeholders. This includes governmental and regulatory authorities, standardization members, as well as others in the healthcare system including those active and interested in the development of international standards for medical technology. The Coalition maintains a terms of reference, action plan, executive committee, and technical secretariat. It is the first public-private partnership with this mission spanning the entire region.



**THE 2005 APEC-OECD INTEGRATED CHECKLIST ON REGULATORY REFORM LAYS OUT A VOLUNTARY GRP FRAMEWORK FOR SELF-ASSESSMENT THAT INCLUDES REGULATORY POLICIES<sup>10</sup>:**

Elements of a foundational, cross-sectoral GRP policy 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 as a basis for technical regulations
- G) Ex-post Assessment (Retroactive review)
- H) Central Regulatory Review, including establishment of a central regulatory oversight/coordination body

**ONE OF THE STRONGEST GRPS IS THE INTERNATIONAL TREATY OBLIGATION OF THE WORLD TRADE ORGANIZATION – TECHNICAL BARRIERS TO TRADE AGREEMENT (WTO/TBT).**

Established in 1994 and constituting international law for its 164 members, the WTO/TBT Agreement aims to ensure that technical regulations, standards, and conformity assessment procedures are non-discriminatory and do not create unnecessary obstacles to trade. At the same time, it recognizes WTO members' right to implement measures to achieve legitimate policy objectives, such as the protection of human health, safety and protection of the environment. The TBT Agreement requires members to base their measures on international standards as a means to facilitate trade. Through its transparency provisions, it also aims to create a predictable trading environment.

**“ARTICLE 2.2** Members shall ensure that technical regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade. For this purpose, technical regulations shall not be more trade-restrictive than necessary to fulfil a legitimate objective, taking account of the risks non-fulfilment would create...”

**ARTICLE 2.3** Technical regulations shall not be maintained if the circumstances or objectives giving

rise to their adoption no longer exist or if the changed circumstances or objectives can be addressed in a less trade-restrictive manner.

**ARTICLE 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...”

<sup>10</sup> <https://www.interamericancoalition-medtech.org/regulatory-convergence/policy/good-regulatory-practices/oecd/>

**THE WORLD HEALTH ORGANIZATION (WHO) GLOBAL MODEL REGULATORY FRAMEWORK FOR MEDICAL DEVICES**<sup>11</sup> “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 well as to jurisdictions that are continuing to improve their regulatory frameworks as they take steps to ensure the quality and safety of medical devices available in their countries.”

Key among the 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. Central to the stepwise approach are the WHO principles of Reliance and Recognition:

- **RELIANCE** is the process whereby a regulatory authority may take into account and give significant weight to (i.e. rely upon) assessments performed by another regulatory authority or other trusted institution in reaching its own decision.
- **RECOGNITION** is the routine acceptance by the regulatory authority of an importing country of the regulatory decision of another regulatory authority or other trusted institution that evidence of conformity with the regulatory requirements of that country is sufficient evidence of conformity with the regulatory requirements of the importing country.

The WHO guidance also reinforces the importance of GRP implementation by medical device regulatory authorities:

“The authority should adhere to good regulatory practices such as creating opportunities to obtain and review meaningful public comment on proposals, assessing regulatory impacts, allowing reasonable transition periods and adopting requirements WHO Medical device technical series that are proportionate and offer the least burdensome ways of achieving policy goals.”

Several regulatory convergence initiatives exist for the medical technology sector:



**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 country in the IMDRF management committee, but countries such as Colombia and Argentina have begun participating in the IMDRF working groups. 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.

Developed by the IMDRF, the **MEDICAL DEVICE SINGLE AUDIT PROGRAM (MDSAP)** allows a recognized Auditing Organization to conduct a single regulatory audit of the good manufacturing practices of a medical device manufacturing facility that satisfies the relevant requirements of the regulatory authorities participating in the program. MDSAP has allowed medical device regulators to economize their resources by relying on one common periodic audit instead of conducting redundant audits already conducted by authorities of different jurisdictions.

In development by the IMDRF, a **MEDICAL DEVICE SINGLE REVIEW PROGRAM (MDSRP)** would allow for a single regulatory premarket review to satisfy the needs of multiple regulatory jurisdictions. Modelled after the MDSAP, the MDSRP is aimed at promoting a harmonized approach to assessing conformity with safety and performance of regulatory requirements. Intended benefits would include: promoting consistency, predictability, transparency, and quality of regulatory programs and criteria for assessing premarket technical documentation for medical devices; greater global convergence of premarket requirements; reduction of regulatory redundancies; medical devices reaching patients more quickly.



## Pan American Health Organization

### PAN AMERICAN HEALTH ORGANIZATION (PAHO), NETWORK FOR REGULATORY AUTHORITIES FOR THE STRENGTHENING OF THE REGULATORY CAPACITY OF MEDICAL DEVICES IN THE AMERICAS

This network of health regulators from across the Americas region meets annually to examine medical device regulatory practices. AdvaMed supports the Network 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.



**STANDARDS ALLIANCE** – AdvaMed implements projects sponsored by the U.S. Agency for International Development (USAID) and the American National Standards Institute (ANSI), to promote Medical Device Regulatory Convergence and foundational Good Regulatory Practices (GRP), providing capacity building and assistance under the Standards Alliance Initiative to several governments of developing countries in Latin America, including Brazil, Colombia, Mexico, Peru and the CAFTA-DR countries.<sup>12</sup> The Standards Alliance Initiative is a funding facility designed to provide capacity-building assistance to designated 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 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.

<sup>12</sup> Dominican Republic-Central America Free Trade Agreement (Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua, Dominican Republic).



## The Pacific Alliance

- CHILE
- COLOMBIA
- MEXICO
- PERU

**THE PACIFIC ALLIANCE** – Chile, Colombia, Mexico and Peru, as members of the Pacific Alliance, are advancing a Medical Device Regulatory Convergence and GRP 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.



### Regulatory Harmonization Steering Committee



Life Sciences Innovation Forum



ASIAN HARMONIZATION WORKING PARTY





# 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, an uneven playing field 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 high-standard 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. Our commitment to the highest standards of integrity will never waiver and only continues to expand. Relunched in 2020, the AdvaMed Code of Ethics on Interactions with Health Care Professionals (“AdvaMed Code”) is a model for the industry



and has been used as a crucial reference for national medical technology sector codes of ethics in Argentina, Brazil, Canada, Chile, Colombia, Ecuador, Mexico, Peru, and dozens of other countries in the Americas 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 implemented by hundreds of organizations and their members across Latin America. As a result of these collective efforts, as of 2019 all medical technology industry associations in the Americas had a high-standard code of ethics for the first time in the region's history. No other industry has achieved this milestone.

## Asia Pacific Economic Cooperation Forum



AdvaMed serves as the industry coordinator for the Business Ethics for APEC SMEs Initiative, the largest public-private partnerships in the world to strengthen ethical business practices in the medical device sector. The annual APEC ethics forums in the Americas featured above include Santiago (2019) and Lima (2016).



AdvaMed supports dozens of partnerships in the Americas that are pioneering effective methods to strengthen ethics and integrity on a multi-stakeholder basis. This includes best practice guidance for third party sales and marketing intermediaries, such as medical technology distributors and supplies, where novel training approaches have been deployed through localized partnerships in Argentina, Brazil, Colombia, and Mexico. Since 2016, AdvaMed joined with the U.S. Department of Commerce to aid in the launch and implementation of the Peruvian and Chilean Consensus Frameworks. These ground-breaking agreements unite ethical business practices in the medical technology sector for more than 40 leading health entities in both countries, including government authorities, industry associations, patient and civil society organizations, and health care professional and provider groups. AdvaMed is also a dedicated partner of the Health Ethics Institute in Brazil (Instituto Ética Saúde) which serves as a multi-stakeholder platform that is orchestrating the first consensus framework outside the APEC region.



## Launch of Peruvian Consensus Framework for Ethical Collaboration



In September 2016, hundreds of delegates representing all leading health stakeholders in Peru convened to sign the world's largest health ethics agreement. The Peruvian Consensus Framework has established a common platform for industry, government, healthcare professionals/providers, and patient organizations to coordinate together in the identification of ethical challenges as well as in the alignment of ethical conduct.



# STRENGTHENING BUSINESS ETHICS & INTEGRITY

## The Inter-American Coalition for Business Ethics in the Medical Technology Sector



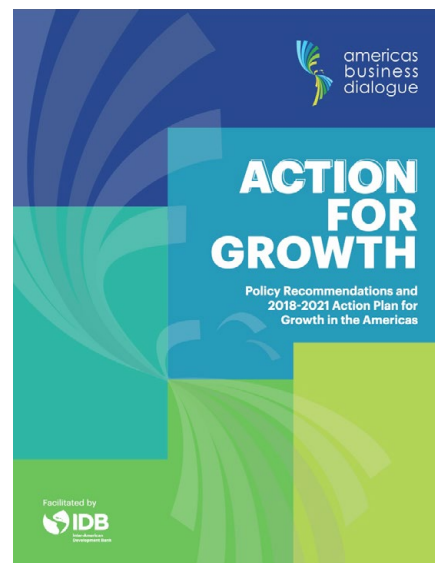
Official launching of the Inter-American Coalition for Business Ethics in the Medical Technology Sector – Bogotá, Colombia (Feb 2017).

Launched in 2017, the Inter-American Coalition for Business Ethics in the Medical Technology Sector brings together 20 national medical technology manufacturer and distributor association in the Americas under harmonized ethical principles as well as a joint action plan to strengthen ethical business practices. Championed by AdvaMed and the Chamber of Medical Device Associations in Latin America (ALDIMED), the medical device sector was the first and remains the only industry to realize a region-wide partnership on ethical business conduct. Since that time, every Coalition member has adopted an aligned code of ethics and implemented has been extended to thousands of companies across the western hemisphere.



Diane Biagiante, Chief Responsibility Officer of Edwards Lifesciences and member of AdvaMed's Global Compliance Steering Committee joins with U.S. Secretary of Commerce Wilbur Ross, IDB President Luis Alberto Moreno, as well as Ministers and senior officials from Brazil, Colombia, and other countries to update the media on the Coalition's work during the 2018 CEO Summit of the Americas.

In 2018, the Coalition was recognized as a model for emulation by Trade Ministers and the President of the Inter-American Development Bank (IDB) during the 3rd CEO Summit of the Americas. The sector's leadership in strengthening ethical business conduct was also featured in the Americas Business Dialogue "Action for Growth" policy recommendations through 2021.



From 2018 to 2020, the Coalition successfully achieved its goal of universal code of ethics adoption by every medical technology industry association in the Americas. This is the first and only sector to realize this achievement and the only region in the world to have realized such progress in ethics harmonization and implementation. The Coalition has set a renewed action plan through 2025 that includes harmonizing the region's advances in ethical third party intermediary relationships with global efforts, the promotion of government strategies to encourage ethical business conduct, the elaboration of multi-stakeholder approaches and consensus frameworks, and enhanced coordination on emerging best practices in ethical business conduct.

Under AdvaMed's joint leadership with ANDI-CDMIS (Colombia) and CCL-COMSAUD (Peru), principals from medical technology enterprises and associations, governments, and other stakeholders from across the Americas gathered in Lima in 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 for Business Ethics in the Medical Technology Sector, bringing together all relevant stakeholders under a common set of ethical principles and a joint action plan. These "Bogota Principles" were launched in 2017 in Colombia and continue to foster the highest standards in ethical business conduct for the medical technology sector in the Americas.



The President of the Medical Device Industry Association of Chile (ADIMECH) and the U.S. Under Secretary of Commerce for International Trade open the sixth meeting of the Coalition in September 2019 in Santiago. The previous five sessions were held in Bogotá (2017), San Jose (2017), São Paulo (2018), Philadelphia (2018), and Buenos Aires (2019).



AdvaMed joins the Inter-American Coalition for Business Ethics in the Medical Technology Sector as a founding member – Bogotá, Colombia (Feb 2017).



In March 2021, after two years of intense preparations, AdvaMed launched the first-ever "Global Distributors Compliance Toolkit"<sup>13</sup> that makes freely available 50 compliance

assets to strengthen ethical third party intermediary relationships across the Americas. These assets include including training slides, forms, communication templates, infographics, and much more that are offered in Spanish, Portuguese, and English. The Toolkit aims to support widespread implementation of the Bogota Principles provisions between medical device companies and their third party intermediaries.

<sup>13</sup> <https://www.advamed.org/member-center/resource-library/global-distributor-compliance-toolkit/>



# HEALTH CARE ACCESS

## Improving Patient Access to Care and Innovative Care Management

Improving patient access to care – and our members’ life-saving and life-improving innovations – is central to AdvaMed’s mission. Included in these innovations are technologies that redesign or in some cases redefine the care pathway to improve efficiency, access and outcomes.



AdvaMed advocates on behalf of our members around the world 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 our work through the Medical Technology Group (MTG) in the UK. MTG is a collaboration between AdvaMed, the Association of British HealthTech Industries (ABHI) and patient groups on issues affecting patient access. MTG advocacy campaigns have included, for example, a focus on unplanned admissions to the UK’s National Health Service, which highlighted the need to better manage chronic conditions to avoid emergency room visits, and a campaign to highlight and combat rationing of treatments and unequal access to care across England. The latter effort spotlighted the practical effect of so-called “postcode lotteries” was that patients in certain areas within England were denied access to necessary care, including 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 provides in returning people to good health as quickly as possible. You can learn more about MTG at [www.mtg.org.uk](http://www.mtg.org.uk).

AdvaMed also collaborates in Germany with BVMed (the German medical technology trade association) on key issues relating to patient access to medical technology. 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 our 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.



## Modernizing Public Procurement Policies

Public procurement policies 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.<sup>14</sup>



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 World Bank's initial emphasis is primarily on capital equipment, AdvaMed's work with the group has resulted in adoption of broad, value-based concepts that are applicable to situations in which governments want to obtain better value. The World Bank continues to dedicate resources in this area, and we will continue to work with them where possible to help ensure greater adoption of these principles in emerging markets.<sup>15</sup>

## Ensuring Appropriate Value-Based Procurement

AdvaMed has formulated principles on value-based care and value-based procurement to help ensure that such practices are transparent and fair, and that they promote patient access to quality care, as an alternative to approaches that too often focus singularly on short term costs. Our work on value-based care centers primarily around the U.S. market, but the principles are instructive to other markets as well.<sup>16</sup>

AdvaMed has also done significant work on value-based procurement with a focus on emerging markets. Many global markets use centralized tenders as the vehicle of choice for health care purchasing. When this centralized authority is utilized it is important for there to be a distinction between cost and value. Too frequently we have seen a short term focus on cost or the imposition of price controls lead to dissatisfaction with the procurement results or short term price reductions accompanied by poor quality.

AdvaMed advocates for the inclusion of transparent, value-based principles in all health care procurements to ensure procurement is able to deliver optimal solutions, value for money and enhanced outcomes. Our work supports processes where a large, multifaceted collection of stakeholders, including industry, government officials, health care professionals, and patient groups, work in a transparent manner to define the goals and performance criteria of procurement, before a procurement is finalized or any bids are solicited. Such processes are a powerful mechanism to deliver value and greater satisfaction with the end results. AdvaMed will continue to work with the World Bank, the U.S. Agency for International Development (USAID), and officials in countries utilizing health care tenders, to help ensure transparent, value-based practices are utilized in health care tenders around the world.

<sup>14</sup> <https://www.advamed.org/payment-health-policy/>

<sup>15</sup> <https://www.worldbank.org/en/projects-operations/products-and-services/brief/procurement-new-framework#overview>; <https://www.worldbank.org/en/projects-operations/products-and-services/brief/industry-engagement-program#health>

<sup>16</sup> <https://www.advamed.org/member-center/resource-library/value-framework-toolkit/>



# INTERNATIONAL AND MULTILATERAL COOPERATION

As the world's largest medical technology industry association, AdvaMed collaborates with leading multi-lateral institutions and private sector alliances. These regional and global partnerships with inter-governmental and multi-stakeholder 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. At the global level, AdvaMed engages with the World Health Organization (WHO), World Trade Organization (WTO), Organisation for Economic Co-operation and Development (OECD), Global Medical Technology Alliance (GMTA), and Global Diagnostics Alliance (GDA). Within Latin America, AdvaMed participates in the

Summit of the Americas and CEO Summit of the Americas, led by the Organization of American States (OAS), and the Americas Business Dialogue (ABD), led by the Inter-American Development Bank (IDB). AdvaMed also partners with the Pacific Alliance, a regional integration initiative that counts Chile, Colombia, Mexico, and Peru as principal members. Moreover, AdvaMed is active within the Asia-Pacific Economic Cooperation forum (APEC) which includes 21 Pacific Rim member economies, including Chile, Mexico, and Peru. AdvaMed and its member companies engage with these institutions and alliances on a significant number of issues, including good regulatory practices and trade, pandemic response, health policy, and ethical business conduct, among others.<sup>17</sup>



Asia-Pacific Economic Cooperation

<sup>17</sup> More information on these organizations can be found at: [who.int/](http://who.int/) (WHO), [wto.org/](http://wto.org/) (WTO), [oecd.org/](http://oecd.org/) (OECD), [globaldiagnosticsalliance.org/](http://globaldiagnosticsalliance.org/) (GDA), [globalmedicaltechnologyalliance.org/](http://globalmedicaltechnologyalliance.org/) (GMTA), [iadb.org/en](http://iadb.org/en) (IDB), [oas.org/en/](http://oas.org/en/) (OAS), [alianzapacifico.net/en/](http://alianzapacifico.net/en/) (Pacific Alliance), [apec.org/](http://apec.org/) (APEC)

# OUR COLLABORATIONS AND PARTNERS

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:

|                  |                |   |  |
|------------------|----------------|---|--|
| <b>ARGENTINA</b> | CADIEM         | Asociación Argentina de Distribuidores e Importadores de Equipos Médicos  | Argentine Medical Equipment Importers and Distributors Association                                 |
|                  | CAPRODI        | Cámara Argentina de Reactivos para Diagnóstico  | Argentine Diagnostic Reagents Chamber  |
| <b>BRAZIL</b>    | 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 Product 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 Produtos para Saúde                                       | Brazilian Health Products Importers and Distributors Association                                   |
|                  | CBDL           | Câmara Brasileira de Diagnóstico Laboratorial   | Brazilian In-Vitro Diagnostics Chamber   |
|                  | IES            | Instituto Ética Saúde   | Brazilian Health Ethics Institute  |
| <b>CANADA</b>    | Medtech Canada | Medtech Canada  | Medtech Canada   |
| <b>CHILE</b>     | APIS           | Asociación de Proveedores de la Industria de la Salud   | Association of Health Industry Providers   |
|                  | ADIMECH        | Asociación Gremial de Dispositivos Médicos de Chile   | Medical Devices Association of Chile   |
| <b>COLOMBIA</b>  | ANDI-CDMIS     | Asociación Nacional de Empresarios de Colombia – Cámara de Dispositivos Médicos                                     | Colombian National Business Association – Medical Device Chamber                                   |
| <b>ECUADOR</b>   | ASEDIM         | Asociación Ecuatoriana de Distribuidores e Importadores de Productos Médicos  | Ecuadorian Medical Product Importers and Distributors Association                                  |

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# OUR COLLABORATIONS AND PARTNERS

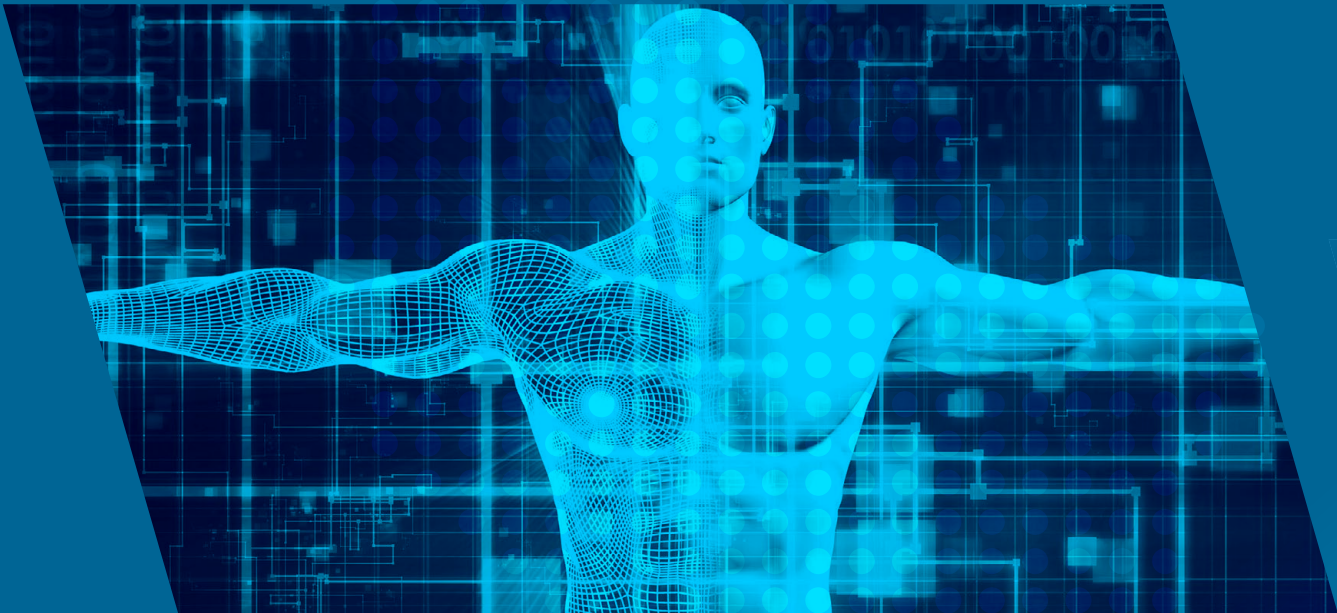
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|------------------|------------------------------------|---|---|
| <b>MEXICO</b>    | AMID                               | Asociación Mexicana de Industrias Innovadora de Dispositivos Médicos                                | Mexican Association of the Innovative Medical Device Industry                                 |
|                  | Dispositivos Médicos<br>CANIFARMA  | Cámara Nacional de la Industria Farmacéutica, División de Dispositivos Médicos                      | National Chamber of the Pharmaceutical Industry, Medical Device Division                      |
|                  | ASEMED                             | Asociación de Empresas Médicas  | Association of Medical Companies  |
| <b>PERU</b>      | CCL-COMSALUD                       | Cámara de Comercio de Lima - Gremio de Salud  | Lima Chamber of Commerce – Health Guild   |
| <b>VENEZUELA</b> | AVEDIM                             | Asociación Venezolana de Distribuidores de Equipos Médicos, Odontológicos, de Laboratorios y Afines | Venezuelan Medical, Orthodontic and Laboratory Equipment and Product Distributors Association |
| <b>REGIONAL</b>  | ALDIMED                            | Asociación Latinoamericana de Gremios de Dispositivos e Insumos Médicos                             | Latin American Alliance of Medical Device Associations  |
|                  | ALADDIV                            | Asociación Latinoamericana de Diagnostico In-Vitro  | The Latin American Alliance for the Development of In-Vitro Diagnostics                       |
|                  | Coalition – Ethics                 | Coalición Inter-Americana de Ética Empresarial para el Sector de Tecnología Médica                  | Inter-American Coalition for Business Ethics in the Medical Technology Sector                 |
|                  | Coalition – Regulatory Convergence | Coalición Inter-Americana para la Convergencia Regulatoria para el Sector de Tecnología Médica      | Inter-American Coalition for Regulatory Convergence for the Medical Technology Sector         |



[HTTPS://INTERAMERICANCOALITION-MEDTECH.ORG/](https://interamericancoalition-medtech.org/)





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