



Inter-American
**Coalition for
Business Ethics**

MEDICAL TECHNOLOGY SECTOR

7th Meeting of the Inter-American Coalition for Business Ethics

Session One | 29 June 2020



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**Coalition for
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MEDICAL TECHNOLOGY SECTOR

Introductions by Principal Members / Technical Secretariat



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Welcome Remarks



Mr. Ian Saunders

Deputy Assistant Secretary for
the Western Hemisphere, U.S.
Department of Commerce



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Overview of 6th Meeting Outcomes and 7th Meeting Agenda



Andrew Blasi

Technical Secretariat



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Setting the Scene: The Coalition's Achievements and Future Ambitions



Sergio Pinto

Chair, AdvaMed Latin America
Compliance Working Group



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Review and Discussion of Coalition Action Items from COVID-19 Webinar



Nancy Travis

AdvaMed (USA)



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Spotlight: 1st Latin America Health Ethics Forum (Spring 2021)



Carlos Gouvea

Executive President, CBDL &
Executive Director, Instituto Ética
Saúde



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Looking Ahead to the 2021 Summit of the Americas



Lynn Costa

Senior Advisor, International
Trade Administration, U.S.
Department of Commerce



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Overview of the Coalition's Action Plan and Progress To-Date



Bruno Boldrin

Executive Director, ABRAIDI
(Brazil)



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Roundtable Discussion and Initial List of Coalition Action Plan Updates



Andrew Blasi

Technical Secretariat



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Summarize Session One Outcomes and Session Two Plans



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7th Meeting of the Inter-American Coalition for Business Ethics

Session Two | 29 June, 2020



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Special Presentations on 2020 Coalition Code of Ethics Updates



INTER-AMERICAN COALITION OF BUSINESS ETHICS

ADVAMED'S REVISED CODE OF ETHICS

Nancy S. Travis
Vice President, Global
Compliance & Governance
AdvaMed

June 29, 2020

ADVAMED CODE REVISIONS

Background/Timeline

- Original AdvaMed Code launched in Sept. 2003 (formerly HIMA Code, eff. January 1993)
- Revised & Restated AdvaMed Code launched in July 2009
- In the intervening 10 years:
 - New government guidance; informative settlements & enforcement actions
 - AdvaMed has issued additional guidance on critical topics (transparency, inventory management, PODs, etc.)
 - Other life sciences associations (PhRMA, MTANZ, MedTech Europe, and others) have launched and revised their own codes
 - AdvaMed launched AdvaMed Code in China, eff. January 1, 2016

Project Goals

- Update language to address challenges under existing Code, reflect evolving standards & business models
- Integrate existing AdvaMed guidance, where appropriate
- Bring FAQs & examples current
- Improve readability & user friendliness in mobile environment

ADVAMED CODE REVISIONS (CONT'D)

Process

- Formed working group of 55+ attorneys and compliance officers to draft updates
- Collected feedback from stakeholders (physicians, medical societies, medical colleges/hospitals, supply chain organizations, sales organizations, former prosecutors)
- November/December 2018 – internal AdvaMed governance process to vet, review, and approve revisions to Code
- December 2018/January 2019 – communication plan to share revisions (and offer individualized training sessions to) provider groups, specialty societies, other life sciences associations, and relevant government agencies
- **Approval & public notification – December 7, 2018**
- **Effective date of revised Code – January 1, 2020**

2019 Efforts

- Graphic artist to further enhance Code appearance
- Created new FAQs & updated tools/resources
- Created virtual Code certification program
- Developed small company resources
- Enhanced Code enforcement and adjudication
- Launched online Code training program
- Issued additional communications

ADVAMED CODE REVISIONS (CONT'D)

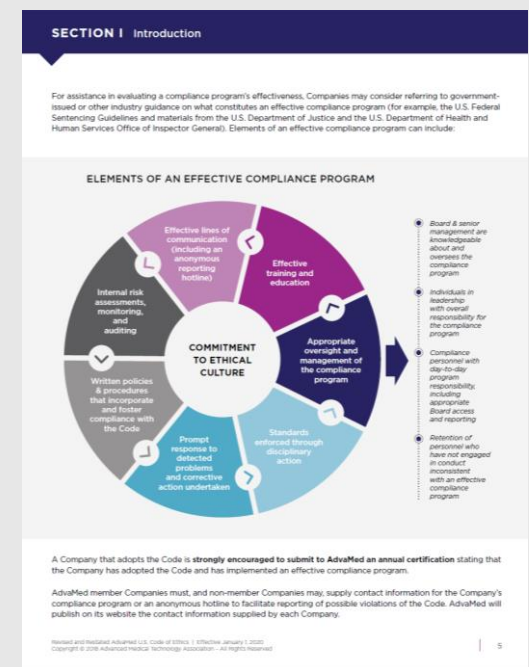
New Cover Page



New Table of Contents

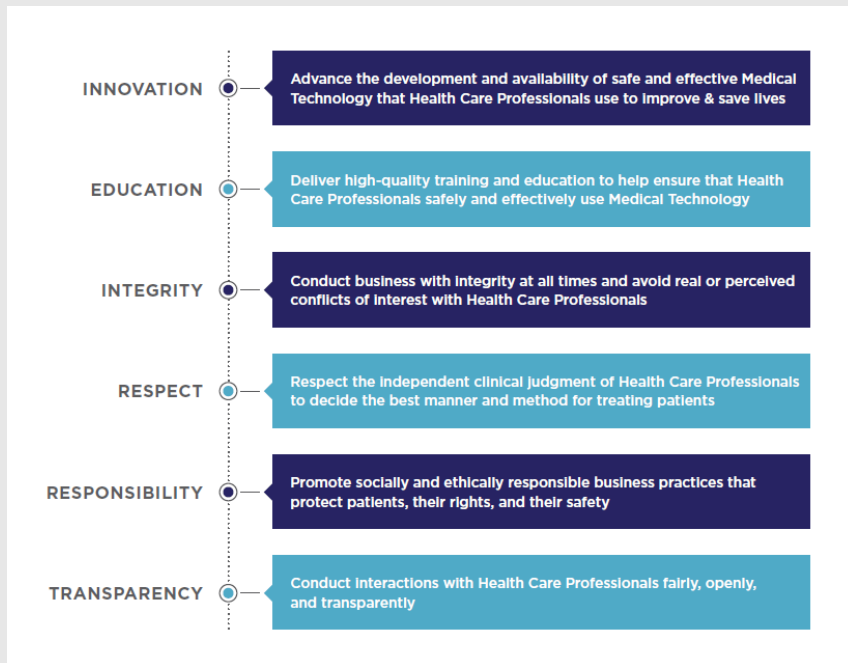
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New Graphics



ADVAMED CODE REVISIONS (CONT'D)

New Cornerstone Values



New Interpretive Principles

Scope & Applicability of the Code

Legal Principles	The Code does not provide legal advice or create legal rights or obligations.
Geographic Reach	The Code applies to all Company interactions with U.S. Health Care Professionals, whether occurring inside or outside the United States (such as at a conference or other event).
Interactions with Health Care Professionals	The Code applies to a Company's interactions and a Company's employees' and agents' interactions with U.S. Health Care Professionals, even if an employee or agent pays for the interaction himself/herself.
Representatives	A Company adopting the Code is required to communicate the Code's provisions to its employees, agents, dealers, and distributors, with the expectation that they will adhere to the Code.
Multiple Business Lines	Companies with different business lines (for example, medical devices, pharmaceuticals, biologics, consumer items, and/or research-only products) may have other industry codes that apply to their businesses. The AdvaMed Code applies to Companies' interactions linked to Medical Technology.
Combination Products	The Code applies to all interactions with U.S. Health Care Professionals related to combination products that include a Medical Technology component (for example, those that are both biologics and devices or drugs and devices), which may also be subject to other trade association codes.



ADVAMED CODE REVISIONS (CONT'D)

New Glossary

Glossary

Commercial Sponsorship	A payment or in-kind support provided to a third party in exchange for advertising or promotional opportunities for the Company (for example, a Company exhibit at a Third-Party Program).
Company	A company that develops, produces, manufactures, and markets Medical Technology.
Educational Grant	A payment or in-kind support to a third-party entity (for example, a Third-Party Program Organizer or a training institution) to reduce the costs of providing education. An Educational Grant is not offered for Commercial Sponsorship opportunities.
Health Care Professionals or HCPs	A Health Care Professional is any person or entity (a) authorized or licensed in the United States to provide health care services or items to patients or (b) who is involved in the decision to purchase, prescribe, order, or recommend a Medical Technology in the United States. This term includes individual clinicians (for example, physicians, nurses, and pharmacists, among others), provider entities (for example, hospitals and ambulatory surgical centers), and administrative personnel at provider entities (for example, hospital purchasing agents). This term does not include Health Care Professionals who are bona fide employees of a Company, while acting in that capacity.
Medical Technology	<p>Medical Technology is a broad term that means medical devices and products, technologies, digital and software platforms, and related services, solutions, and therapies used to diagnose, treat, monitor, manage, and alleviate health conditions and disabilities. Some examples include:</p> <ul style="list-style-type: none">• Implantable medical devices that are placed in or on the human body to replace, repair, or strengthen a body part;• Surgical devices used to perform procedures;• Digital technology and software platforms that assist in monitoring, diagnosing, and treating patients; and• Non-invasive reagents, instrumentation, and/or software to aid in the diagnosis and treatment of patients; among other technology.
Modest	Moderate value, but may differ depending on regional differences
Occasional	An interaction is considered occasional if it occurs infrequently and not on a routine basis

New Summary: Value of HCP Interactions



Companies and Health Care Professionals advance medical care and clinical science through **research, product development, and product testing** that results in new or improved, innovative Medical Technology



Companies **instruct, educate, and train** Health Care Professionals on the safe and effective use of complex Medical Technology



Companies provide **product service and technical support** for Health Care Professionals to help ensure the safe and effective use of Medical Technology



Companies support Health Care Professionals' **scientific and medical research**, as well as the **enhancement of clinical skills and educational opportunities** to improve patient care



Companies promote **charitable giving and public awareness** of medical and health conditions through grants and donations in support of indigent care and patient education



ADVAMED CODE REVISIONS (CONT'D)

Introduction:

- Consolidates existing Preamble and Code Compliance section
- New defined terms: Commercial Sponsorship; Educational Grant; Satellite Symposium; Third-Party Program; Third-Party Program Organizer
- Enhanced definitions: Medical Technologies; HCP

Consulting:

- Content remains primarily the same
- Adds clarifying language on what is “legitimate need”
- Includes callout explanation of how to develop a fair market value methodology
- Explains why sales’ role is limited under the Code
- Adds callout box highlighting that physicians may have conflicts of interest that require mitigation
- Includes language requiring confirmation of services before making payment

SECTION II Consulting Arrangements with Health Care Professionals

KEY CONCEPTS

Companies rely on Health Care Professionals' expertise in a variety of important ways, such as training on the safe and effective use of Medical Technology, conducting research, and developing product advancements that lead to safer and more effective treatments for patients.	Based on legitimate need, Companies engage Health Care Professionals through written contracts that document the Health Care Professional's services and any fair market value compensation for those services.
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A. Engaging a Health Care Professional to Provide Consulting Services

Companies engage Health Care Professionals to provide a wide-range of valuable, bona fide consulting services. Some examples include arrangements for a Health Care Professional to provide education and training, speaking services, proctoring and preceptorships, reference center or center of excellence services, participation in advisory boards or focus groups, medical technology development and research services arrangements (such as research and development, clinical studies, clinical investigator services, collaborative research, and post-market research), and arrangements for the development or transfer of intellectual property.

Companies should apply the following principles to all consulting arrangements with Health Care Professionals:

- **Legitimate Need.** A Company should enter a consulting arrangement with a Health Care Professional only if it has identified a legitimate need for the Health Care Professional's services in advance.
- **Consultant Selection.** A Company should select only duly vetted Health Care Professionals to serve as consultants, based on the Health Care Professional's qualifications to meet the identified need. Some examples of these qualifications include the Health Care Professional's specialty, years of experience, location, practice setting, clinical research experience, podium presence, speaking and publication experience, or experience with, usage of, or familiarity with a specific Medical Technology, among other qualifications.

A Company may not select or compensate consultants as a reward for past usage or as an unlawful inducement for future purchases. A Company should implement safeguards so that consultants are not selected based in whole or in part on sales considerations.

ADDITIONAL INSIGHTS

A legitimate need arises when a Company requires the services of a Health Care Professional to achieve a specific objective, such as the need to train Health Care Professionals on the technical components of safety and effectively using a product, the need for clinical expertise in conducting product research and development, or the need for a physician's expert judgment on clinical issues associated with a product. Designing or creating an arrangement to generate business or to reward referrals from the contracted Health Care Professional or anyone affiliated with the Health Care Professional are not legitimate needs for a consulting arrangement.

Revised and Restated Advanced U.S. Code of Ethics 1.0 Effective January 1, 2020
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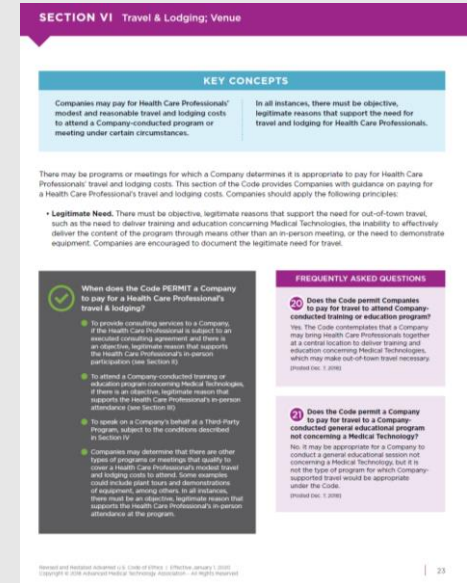
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ADVAMED CODE REVISIONS (CONT'D)

- **Company Programs:**
 - Consolidates existing sections on training & education and other business meetings
 - Parameters for all company-conducted programs
 - Content remains largely the same, focused on setting, appropriate faculty, and legitimate need
- **Third-Party Programs:**
 - Merged existing sections on support for third-party educational, charitable, and research programs
 - Educational Grants – content largely the same:
 - ✓ Creates distinction between Educational Grant (funding to defray costs of putting on education) and Commercial Sponsorship (new terminology) (reasonable fee paid in exchange for ad/promo opportunities)
 - ✓ Removes statement that conference organizer must be responsible for content, speakers, attendees, and materials, focusing instead on adhering to conference/accreditation standards that might apply
 - ✓ Allows companies to send speaker to Third Party Program, provided the Third-Party Organizer sanctions it and appropriate disclosures are made
 - ✓ Includes new “Educational Grant Review Process” checklist for companies to use when assessing whether to fund an Educational Grant
 - ✓ Includes new FAQ indicating that companies can’t give HCPs any benefit that the company has received in exchange for its financial support of a third party’s program
 - ✓ Includes new FAQs on satellite symposia and when it is OK to pay for travel/lodging for third-party program attendees
 - Charitable Donations & Research Grants – Content is largely the same; incorporates existing FAQs; clarifies parameters for funding donations and research grant requests

ADVAMED CODE REVISIONS (CONT'D)

- **Co-Conducted Education & Marketing:**
 - New section on jointly-conducted education and marketing programs
 - Requires legitimate need for the program; appropriate company controls (including requiring HCP to meet company's off-label HE&R guidelines); content should be balanced between and company; equitable contributions towards activity and cost; subject to written agreement)
- **Travel:**
 - New section that consolidates existing travel guidance, provides clarification on when travel is permitted (consulting, company training, legitimate need for meeting and HCP presence) and when travel is prohibited (general education; attending Third-Party Program; no legitimate need)
 - Includes additional information on evaluating appropriate venues for meetings (central location, conducive to exchange of information, no top category or luxury hotels)
- **Meals** – Consolidates all guidance on meals into one section, adds language encouraging companies to develop meal policies & to review benchmarking information for support



ADVAMED CODE REVISIONS (CONT'D)

- Communications & Technical Support – Two new sections on:
 - Describes principles for communicating information on unapproved or uncleared uses of products:
 - ✓ Company representative must have appropriate expertise
 - ✓ Communications must be truthful & non-misleading
 - ✓ Information on off-label uses should be identified as such
 - ✓ Includes note for Companies to reference existing guidance – including judicial decisions – in developing policies
- Principles for company representatives providing technical support in the clinical setting
 - ✓ Must be present at the request & under supervision of HCP;
 - ✓ No medical decision-making;
 - ✓ Must comply with applicable patient privacy requirements;
 - ✓ Must comply with applicable hospital/facility policies; and
 - ✓ Cannot provide to eliminate an HCP's overhead expense)

SECTION XIII Company Representatives Providing Technical Support in the Clinical Setting

KEY CONCEPTS

Access to truthful and non-misleading information relating to Medical Technologies is critical to a Health Care Professional's ability to exercise his or her medical judgment, to provide high-quality care, and to safely use available Medical Technology.

Companies are encouraged to apply the principles outlined in this section and develop related controls.

Company representatives may play an important role in the clinical setting by providing technical support on the safe and effective use of Medical Technology. Some examples include:

- Company representatives may need to explain how a Medical Technology's unique settings and technical controls function and may make recommendations.
- Company representatives may assist the clinical/operating room team to ensure that the appropriate range of necessary devices and accessories are available during a procedure, especially when dealing with Medical Technology that involves multiple devices and/or accessories.

Companies should apply the following principles:

1. Company representatives should enter and be present in the clinical setting only at the request of and under the supervision of a Health Care Professional.
2. Company representatives should be transparent that they are acting on behalf of the Company in a technical support capacity.
3. Company representatives should not interfere with a Health Care Professional's independent clinical decision-making.
4. Company representatives should comply with applicable hospital or facility policies and requirements, including patient privacy and credentialing requirements.
5. A Company's technical support should not eliminate an overhead or other expense that the Health Care Professional should otherwise incur while providing patient care.



Revised and updated: Advanced U.S. Code of Ethics - Effective January 1, 2020.
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ADVAMED CODE REVISIONS (CONT'D)

- **Demonstration & Evaluation Product:**
 - Enhances existing language with clarity on when it is acceptable to provide evaluation products and contents of evaluation agreement
 - Adds language that companies should be mindful of transparency requirements
 - Adds language on consignment products and recommendations for controls
- **Branded Promotional Items; Entertainment & Recreation** – content remains primarily the same
- **Providing Coverage, Reimbursement and Health Economics Information** – content remains primarily the same

ADVAMED CODE: FOCUS OF WORK IN 2020

- **COVID Pandemic Compliance Guidance**
 - Affirming high standards of business ethics
 - Ensuring donations, volunteers and training logistics (e.g. providing meals) are appropriate and transparent
 - Communicating strong support from company leadership
- **Education**
 - Medical Societies
 - Third parties, particularly distributors
- **Global Coalition Support**
 - Inter-American Coalition for Business Ethics
 - Business Ethics for APEC SMEs Initiative
 - GMTA Global Compliance Network



AMID Code of interactions with HCPs Recent Improvements

- AMID members to ensure **Commercial Intermediaries** adherence to Code (**written form**)
- **Demo Equipment** → Maximum term (1 year)
- Zero gifts policy → suppression of **courtesies**
- No sponsorship at Paradisiac places: addition of Puerto Vallarta



AMID Code of interactions with HCPs

Recent Actions

- Annual training (October 2019)
 - a. 250 distributors, 100 members
 - b. Panels with industry stakeholders / sharing of **best business practices**
 - c. Presence of the Mexico's Department of Government Affairs (SFP)
- Partnership with Executive Secretary of the National Anticorruption System (SESNA): trainings
- Training to 180 Public Sector physicians "Centro Medico La Raza"
- Guidelines: Donations, procurement and factories



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MEDICAL TECHNOLOGY SECTOR

Review 2019 Coalition Member Association Report & Designing and Executing the 2020 Coalition Member Association Survey



Ethan Gumpert

AdvaMed



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Update on AdvaMed Distributor Working Group and Virtual Toolkit / Modules



Ethan Gumpert

AdvaMed

PROJECT CHARTER

The AdvaMed Distributor Compliance Capabilities (ADCC) Project would consist of two separate and distinct Workstreams:

- A. Creation of standard Distributor Compliance Program materials and implementation training/curriculum to be delivered to and implemented by distributor employees
- B. Creation of an AdvaMed Strategy and Campaign to disseminate and drive adoption of Program by industry associations, distributor associations, and member companies

PROJECT PHASES 1 & 2: WORKSTREAM A

The AdvaMed Distributor Compliance Capabilities (ADCC) Project would consist of two separate and distinct Workstreams:

- A. Creation of standard Distributor Compliance Program materials and implementation training/curriculum to be delivered to and implemented by distributor employees
 - Phase 1 (September - December) Draft Introductory Toolkit Material
 - Phase 2 (February - April) Draft Substantive Toolkit Material
- B. Creation of an AdvaMed Strategy and Campaign to disseminate and drive adoption of Program by industry associations, distributor associations, and member companies

WORKSTREAM A WORKING GROUP

AdvaMed Distributor Capacity Building Working Group

Boston Scientific

- ❖ Pamela Panagian, Senior Manager, Communications, Training & Third-Party Compliance (USA)

Cardinal Health

- ❖ Carmen Guerra Manager, Compliance Business Partner, LATAM (USA)
- ❖ Fernanda Garay, Mexico Legal Counsel (Mexico)

Edwards Lifesciences

- ❖ Tiffany Chang, Senior Manager, Compliance Policies, Training & Communications (USA)

Elekta

- ❖ Roberto Heckmann, Vice President & Regional Chief Compliance Officer, (USA)

Johnson & Johnson

- ❖ Michelle Wagner, AdvaMed Working Group Chair, Global Lead, Third-Party Intermediary & Supply Chain Compliance (Australia)

Zimmer Biomet

- ❖ Daniel Bork, Vice President, Global Third-Party Compliance (USA)

Smith & Nephew

- ❖ Caterina Szafranski, Compliance Senior Director Latam & Global Third-Party Compliance (Colombia)

Stryker

- ❖ John Roudabush, Senior Director, Global Indirect Channel Management (Switzerland)

Wright Medical

- ❖ Tamara Tubin, International Compliance Director, Corporate Compliance (Switzerland)

Medtronic

- ❖ Nieves Jiste, Senior Director, Global Channel Compliance (Spain)
- ❖ Eulalia Mesanza Costa, Global Channel Compliance, Finance & Business Controller, EMEA (Spain)

WORKSTREAM A: PROGRESS

Global Distributor Compliance Toolkit - Conception

Phase 1

1. Gathered existing company and association material
2. Worked through and re-drafted existing material to narrow concept and build foundation
3. Completed introductory material and created the Key Areas of Global Compliance



**RECOGNIZING
GOVERNMENT
OFFICIALS**



**IDENTIFYING
CONFLICTS OF
INTEREST**



**PREVENTING
BRIBERY &
CORRUPTION**



**KEEPING GOOD
BOOKS & RECORDS**



**INTERACTING WITH
HEALTH CARE
PROFESSIONALS &
GOVERNMENT
OFFICIALS**



**REPORTING A
CONCERN**

WORKSTREAM A: PROGRESS

Global Distributor Compliance Toolkit - Conception & Creation

Phase 1

1. Gathered existing company and association material
2. Worked through and re-drafted existing material to narrow concept and build foundation
3. Completed introductory material and created the Key Areas of Global Compliance

Phase 2

1. Gathered remaining existing material
2. Built substantive toolkit material upon the foundational intro material and Key Areas concept

THE TOOLKIT TODAY

Overview Material – 5 assets

Material

Key Areas of Global Compliance Intro Deck

Global Distributor Toolkit Postcard

Global Distributor Center Webpage Front

Templates & Forms Overview

Global Distributor Compliance Toolkit Compendium

Digital Drafts – 2 assets

- [360 Articulate GDC Toolkit](#)
- [AdvaMed Global Distributor Center](#)

	Recognizing Government Officials	Identifying Conflicts of Interest	Preventing Bribery & Corruption	Keeping Good Books & Records	Interacting with HCPs & GOs	Reporting a Concern
Introductory Slide(s)	Definition	Definition & Examples	Definition & Example	Musts & Must Nots	Definition & Examples	Contact Info
Training Slide(s)	Examples				Five Principles	
					Meals	
					Gifts & Entertainment	
					Charitable Donations	
					Sponsorship of an Individual HCP	
					Research & Education Grants	
					Public Tenders	
					Demonstration Products & Samples	
					Example Scenarios	
Case Studies	Parisian Surgeon	Your Spouse	Product Training	Documenting Dinner	Business Dinner	
	Public Tender	New Sales Rep	Conference Booth	Hiding Illegal payments	Small Talk	
	Know Your Customer		Customs Official	Financial Controls & Bookkeeping	Travel Request	
			Procurement Officer		Concert Tickets	
					State Monument	
					Free Samples	
Infographic		Identifying Conflicts of Interest	Preventing Bribery & Corruption	Keeping Good Books & Records	Interacting with HCPs & Gos	
Templates & Forms		COI Declaration	Self Certification Form	Expense Reimbursement Form	HCP Meeting, Event or Training Packet	
			Sponsorship Packet	Notification on Use of Sub Distributors	HCP Sign-in Sheet	
			Grant or Donation Packet			
Guidance			Due Diligence Quick Check	Keeping Good Books & Records Guidance	Code of Conduct	
Other					Do's & Don'ts Brochure	Speak Up Postcard

EXAMPLES: OVERVIEW MATERIAL

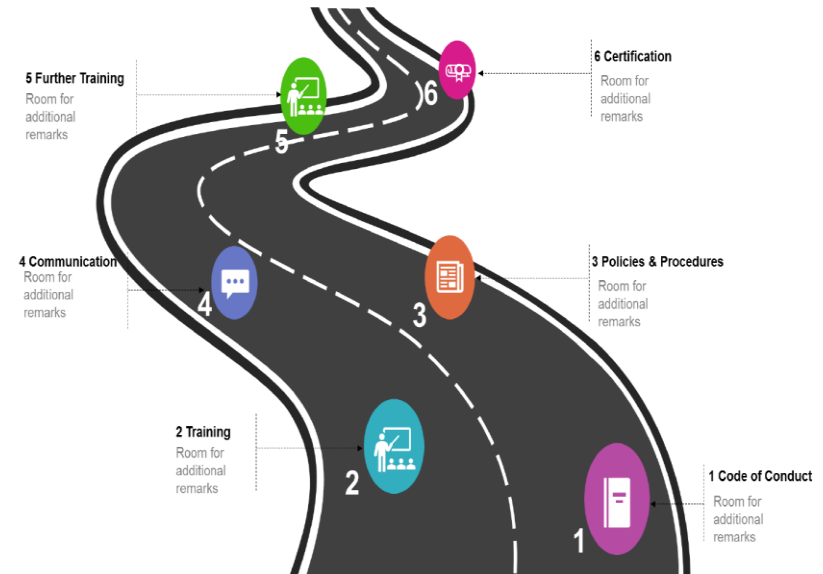
Toolkit material overviews

OVERVIEW TEMPLATES & FORMS

To help you meet your compliance requirements, we are providing a number of reference documents, tools and templates for your use. Some of these documents can be used as they are while others may require modification and adjustments in order to be used properly given that local laws, regulations, or industry codes may include additional or different requirements. Some documents may not be relevant to your regular business operations.

Conflict of Interest Declaration	<p>A conflict of interest occurs when a personal activity, relationship or business involvement interferes — or appears to interfere — with our ability to fulfill our job responsibilities. We make business decisions based on what is in the best interest of our Company and not for personal gain or benefit. All employees should proactively and promptly disclose actual or perceived conflicts of interest. An example conflict of interest may be if you have a family member working in a hospital where your company provides products or services.</p> <p>This template can be used to disclose actual, perceived or potential conflicts of interest in a timely and effective manner. It can also be used to document the decision made on how the conflict of interest is resolved.</p>
Due Diligence Quick Check (Guidance)	<p>Due diligence is the investigation or exercise of care that a business or person is expected to take before entering into an agreement or contract with another party.</p> <p>This guidance document explains what is required if you appoint another party to sell, market, deliver and/or promote products or services and guidance on documenting the performance of due diligence on any business partner used or to be used in the fulfillment of a distribution agreement.</p>
Expense Reimbursement Spreadsheet	<p>This spreadsheet can be used to support and document any expenses you incur in the course of business activities including but not limited to hospitality, business travel, meetings and expenses related to interactions with customers and suppliers. Companies should establish spending limits for business related expenditures, such as meals, refreshments, or lodging as per local laws, regulations and industry codes.</p>
Grant or Donation Packet	<p>Use this packet when agreeing to fulfill a grant or donation request. Templates included:</p> <ol style="list-style-type: none"> 1. Grant/Donation Request - To request approval internally to provide a grant or donation. 2. Grant/Donation Agreement - To document your donation or grant agreement with the recipient of the funds.

Webpage menu/landing page



This toolkit is a step by step guide to help you implement a compliance program within your business. Your compliance program should start with a Code of Conduct. The toolkit contains a sample Code of Conduct which will help your employees, officers and directors understand and ensure business is conducted in an ethical, lawful and appropriate manner.

The next step is conducting training for all employees. The toolkit contains some training material that you can customize for your needs to train your employees

EXAMPLES: INTRO & TRAINING SLIDES

Definitions



Recognizing Government Officials

What do we mean when we say Government Officials?

A Government Official is:

Any official or employee of a government agency or other governmental unit or public international organization, along with officers and employees of government owned companies or companies substantially controlled by such governments.

Do's and Don'ts



Interacting with Health Care Professionals & Government Officials

Gifts & Entertainment

You may not:

- ▶ Provide gifts to the personal guest of an HCP or GO.
- ▶ Provide entertainment or recreation to an HCP or GO.
- ▶ Provide cash or cash equivalents such as gift certificates to an HCP or GO.

EXAMPLES: CASE STUDIES

Multiple choice challenges



Identifying Conflicts of Interest

Your Spouse: Part 2

Your spouse works as a Health Care Professional (HCP) at a hospital where they have authority over some purchasing decisions. Your company is attempting to sell products to this hospital. What steps should you take to avoid all potential conflicts of interest?

- A. Disclose the above situation in advance to your primary supplier contact.
- B. If you are not certain if this could be a potential conflict of interest, contact [insert compliance contact/information source] for additional information.
- C. Refrain from selling or promoting products at the hospital until you've addressed the situation with the company.
- D. All of the above.

The correct answer is D.

This is a potential conflict of interest between your interests and those of your Company and Business Partners. You must disclose all possible conflicts of interest in advance. If you are not certain if a conflict of interest exists, you can always contact [insert company contact] with questions or to request guidance.

Scenario studies



Keeping Good Books & Records

Hiding Illegal Payments

A Distributor partnered with a Marketing Services Company. Several months after the partnership was formed, the Distributor audited the Company's transactions and discovered a section for "marketing payments" in the Company's books and records that had been used to facilitate improper payments to health care professionals. Company employees were using these accounts to bribe employees of the Ministry of Health. Payments were also made to employees from state owned companies with influence over purchasing decisions related to the Company's products.

After finding these payments inside the Company's books and records, the Distributor terminated all other marketing accounts to stop this practice.

Seasonal books and records audits are a good risk mitigation measure to detect the use of accounts hidden in books and records to commit crimes like fraud or to hide illegal payments to government officials.

EXAMPLES: INFOGRAPHICS

PREVENTING BRIBERY & CORRUPTION

Bribery & corruption are global issues and are taken seriously by governments worldwide. Bribery of Government Officials is a crime under local and international law; for example, the U.K. Bribery Act and the U.S. Foreign Corrupt Practices Act, among others.

Corruption is not limited to bribery. Global and local anti-corruption laws prohibit activities including, but not limited to, embezzlement, extortion, and the hiring or advancement of certain people for private or political gain.

→ You are responsible for following **all** applicable local & international anti-bribery and anti-corruption laws.

→ Failing to follow anti-bribery and anti-corruption laws can result in severe civil and criminal penalties as well as reputational harm for you as an individual, your company & business partners.

Global companies have been found responsible for inappropriate actions taken by their distributors around the world to gain an improper business advantage. For example, in 2012 a global medical device company was fined \$22M USD by U.S. authorities for paying bribes through distributors in Europe to win business.



PUTTING IT INTO PRACTICE...

- You are participating in a tender on behalf of a medical device manufacturer. The hospital's procurement officer tells you she will select your company to win the tender if you give her spouse a job in your company.
- You are waiting for a shipment of medical device products. A government customs official tells you he'll speed up the import paperwork for an additional fee of \$50 USD.

WHAT SHOULD YOU DO?

For both scenarios, you should refuse the request and report the request immediately. No payments should be made to expedite routine government services, nor should unauthorized payments be made to Government Officials in connection with their duties.

It's important to note that bribery takes many forms; it is not always financial in nature. Hiring a relative or friend of a decision maker in return for receiving a favor is also a bribe. You must never accept or agree to a favor in exchange for company business even if it is considered "normal" or "customary" in your country of business.

You will never be penalized for making a good faith report of inappropriate conduct, and you should report this behavior to your employer immediately.

EXAMPLES: TEMPLATES & FORMS

Communication templates

Employer Notification

[Date]

[Name, address of HCP employer]

Dear [HCP employer name],

[Company name] has invited [HCP name] to attend [name of meeting/event/training].

This [meeting/event/training] will provide [describe purpose of meeting/event/training]. Please see the attached agenda for further details.

This invitation is not being extended in exchange for the use, recommendation, prescription, or influence on the use of [company name] products, or with regard to the value or volume of business generated between the parties. Per [company name] Code of Conduct, we do not offer anything of value.

We will provide the following: [customise as appropriate]

- Reasonable meals and refreshments during the [meeting/event/training]
- Transportation to and from the [meeting/event/training]
- Reasonable accommodation from [insert dates]

If you approve of this activity, no action is required. If we do not receive a reply from you, we will assume that you approve of our offer to invite [HCP name] to [name of meeting/event/training].

If you do **not** approve of this activity, please contact [contact details] stating your disapproval. Please provide your response by [insert date].

Best regards,

[Name]

[Title]

[Company Name]

cc: [insert name of healthcare professional selected to attend meeting or event]

Request forms

Grant/Donation Request Form

Request form	
Choose the grant or donation type (see attached list for more details)	<input type="checkbox"/> Charitable Contribution <input type="checkbox"/> Healthcare Education / Public Education <input type="checkbox"/> Fellowship / Scholarship <input type="checkbox"/> Research <input type="checkbox"/> Medical Equipment, Supplies, etc. <input type="checkbox"/> Other _____
Provide details of the funding, equipment or services to be provided	
Requesting Organization	
Organization Name	
Contact Person	
Address	
ZIP / City	
Country	
Phone / Fax-Numbers	
E-Mail	
Provide a description of the organization's charitable, educational or scientific purpose	
State the specific purpose of the requested Grant or Donation	<input type="checkbox"/> Education: describe the type of educational event, date, location, name and attach any available brochures or printed information; identify the intended target audience: <input type="checkbox"/> Fellowship: provide the dates, details and location of the program, cost breakdown and provide any available materials, including application forms:

EXAMPLES: GUIDANCE

Detailed best practices/principles

[Insert Company Name / Logo]

KEEPING GOOD BOOKS & RECORDS

Transactions must be recorded timely and accurately in order to assess our company's financial position. Detailed records and supporting documentation are required to evidence the business purpose of our transactions and ensure our books and records are complete and accurate. Supporting documentation includes, but is not limited to, items such as: invoices, receipts, agreements, amendments, and approval forms. Alteration, falsification and destruction of required books and records are serious violations.

1. BENEFITS OF ACCURATE BOOKS AND RECORDS

Maintaining accurate books and records that reflect the nature of transactions are beneficial as it allows us to make better business decisions, quickly respond with proper documentation in the case of an audit, and separate transactional information for each of the manufacturers for which we sell product.

2. CASH PAYMENTS

Limiting the amount of cash or cheques used as a form of payment in any transaction is best practice. To the extent that cash is the only option for payment specific documentation must be retained for company records such as detailed receipts.

3. SUPPORTING DOCUMENTATION REQUIREMENTS

Complete supporting documentation should be retained for all transactions. Here are some examples:

a. Employee Expense Reports

- i. Expense approvals.
- ii. Original itemized receipts.
- iii. Explanation of the business purpose for each expense.

b. Disbursements (e.g., payments to vendors, suppliers, etc.)

- i. Contracts, written agreements and addendums.
- ii. Purchase orders.
- iii. Invoices detailing amounts, dates of service and the types of services and/or products received
- iv. Internal approvals.
- v. Proofs of performance (e.g., delivery notices, materials, presentations).
- vi. Proof of payment (e.g., cancelled check, bank statement, wire transfer advice).
- vii. Correspondence.

c. Grants, Donations and Sponsorships

- i. Documentation to evidence the request and business justification (e.g., HCP invitation letter prior to transaction / proposal, program agenda, etc.).
- ii. Transportation, lodging and meal documentation.

Summary guidance/code of conduct

[Insert Company Name / Logo]

Code of Conduct

Introduction

[Insert company name] is committed to maintaining the highest ethical standards in the execution of our business duties while complying with all applicable laws and regulations. This document is not intended to be a substitute for more detailed policies that relate to standards of conduct, if applicable.

[Insert company name] reputation is important. [Insert company name] employees shall not engage in any misconduct that could jeopardize the Company's reputation, its client, or third-party relationships, as well as avoid situations that have any appearance of impropriety. No bribes should be offered, requested, paid or accepted. *[This paragraph should be customized to your Company's vision, mission and values]*

Company resources should only be used for legitimate business purposes in the best interest of [Insert company name]. Incidents, risks and issues contrary to this document should be reported to [Insert relevant person(s)/department(s)].

The Code of Conduct will apply to all officers, directors, employees (including new employees at time of hiring) and all relevant business partners, such as sub distributors and agents.

Basic Principles

1. Compliance with Laws

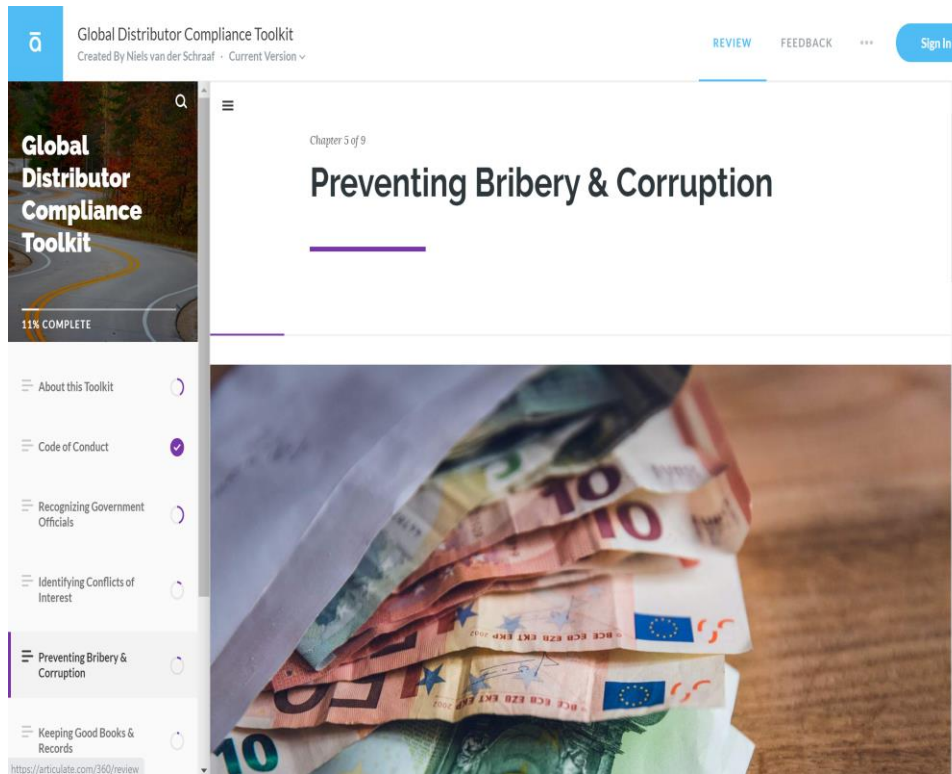
[Insert company name] will conduct its business and affairs in compliance with all applicable laws, rules and regulations and in accordance with [Insert company name] Code of Conduct and its underlying policies and procedures.

2. Conflict of Interest

A conflict of interest occurs when a person's private interest interferes or appears to interfere in any way with [Insert company name]'s interests and may also arise when the Company, employee, director, or a member of his or her family receives improper benefits because of his or her position within [Insert company name]. These situations include, but are not limited to, relationships with government officials, health care professionals, health care organizations, physician owned companies, or any other situation where it may appear that company decisions can be influenced by personal interests or relationships. You should avoid a conflict, or an appearance of a conflict, between your personal interests, your official responsibilities and your Company's interests. Any potential conflict of interest should be declared.

EXAMPLES: DIGITAL DRAFTS

360 Articulate GDC Toolkit



AdvaMed Global Distributor Center



THE TOOLKIT TODAY – QUESTIONS & DISCUSSION

Overview Material – 5 assets

Material
Key Areas of Global Compliance Intro Deck
Global Distributor Toolkit Postcard
Global Distributor Center Webpage Front
Templates & Forms Overview
Global Distributor Compliance Toolkit Compendium

Digital Drafts – 2 assets

- [360 Articulate GDC Toolkit](#)
- [AdvaMed Global Distributor Center](#)

Toolkit Content – 51 assets

	Recognizing Government Officials	Identifying Conflicts of Interest	Preventing Bribery & Corruption	Keeping Good Books & Records	Interacting with HCPs & GOs	Reporting a Concern
Introductory Slide(s)	Definition	Definition & Examples	Definition & Example	Musts & Must Nots	Definition & Examples	Contact Info
Training Slide(s)	Examples				Five Principles	
					Meals	
					Gifts & Entertainment	
					Charitable Donations	
					Sponsorship of an Individual HCP	
					Research & Education Grants	
					Public Tenders	
					Demonstration Products & Samples	
					Example Scenarios	
Case Studies	Parisian Surgeon	Your Spouse	Product Training	Documenting Dinner	Business Dinner	
	Public Tender	New Sales Rep	Conference Booth	Hiding Illegal payments	Small Talk	
	Know Your Customer		Customs Official	Financial Controls & Bookkeeping	Travel Request	
			Procurement Officer		Concert Tickets	
					State Monument	
					Free Samples	
Infographic		Identifying Conflicts of Interest	Preventing Bribery & Corruption	Keeping Good Books & Records	Interacting with HCPs & Gos	
Templates & Forms		COI Declaration	Self Certification Form	Expense Reimbursement Form	HCP Meeting, Event or Training Packet	
			Sponsorship Packet	Notification on Use of Sub Distributors	HCP Sign-in Sheet	
			Grant or Donation Packet			
Guidance			Due Diligence Quick Check	Keeping Good Books & Records Guidance	Code of Conduct	
Other					Do's & Don'ts Brochure	Speak Up Postcard

THE TOOLKIT TOMORROW

Global MedTech Distributor Center

Global Compliance Toolkit

- Digitization
 - Graphic re-design
 - Translations
- Toolkit utilization tutorials
- Searchable indexes of material

Global Compliance Institute

- Online training courses
 - Phased/maturity learning
 - Mechanism to track training progress/level of compliance program maturity

Global Distributor Database

- Database listing all distributors trained & level of training
- Distributor profiles that list the above plus:
 - Region
 - Products
 - Contact information
- Robust search functions to maximize utility for manufacturers seeking ethically-minded distributors

THE TOOLKIT TOMORROW – QUESTIONS & DISCUSSION

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LAST NOTE – WORKSTREAM B IS YOU

The AdvaMed Distributor Compliance Capabilities (ADCC) Project would consist of two separate and distinct Workstreams:

- A. Creation of standard Distributor Compliance Program materials and implementation training/curriculum to be delivered to and implemented by distributor employees
- B. Creation of an AdvaMed Strategy and Campaign to disseminate and drive adoption of Program by industry associations, distributor associations, and member companies



Inter-American
**Coalition for
Business Ethics**

MEDICAL TECHNOLOGY SECTOR

Summarize Session Two Outcomes and Session Three Plans



Inter-American
**Coalition for
Business Ethics**

MEDICAL TECHNOLOGY SECTOR

7th Meeting of the Inter-American Coalition for Business Ethics

Session Three | 30 June 2020



Discussion on Coalition Collaboration with the Americas Business Dialogue (ABD) and the Inter-American Development Bank (IDB)

1. Measuring the Positive Impact of Ethical Conduct
2. Government Strategies to Encourage Ethical Business Conduct
3. 2021 Summit of the Americas



Inter-American
**Coalition for
Business Ethics**

MEDICAL TECHNOLOGY SECTOR

Concluding Remarks from Coalition Executive Committee Members



Bruno Boldrin
ABRAIDI (Brazil)



Inter-American
**Coalition for
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MEDICAL TECHNOLOGY SECTOR

Concluding Remarks from Coalition Executive Committee Members



**Marisol Sanchez
& Gildardo Romero**
ANDI-CDMIS (Colombia)

TRAINING AND EDUCATION

Ethic Code release, socialization and certification..

<http://www.andieticadispositivosmedicos.com/>.

We have 1.667 people trained



COLLABORATION- ANDI ETHICS COMMITTEE MEETING

- Monthly meetings – Collaborative effort focus on resolution of inquiries made by affiliate or not affiliate companies as well individuals.
- 3 sub committees focus on key aspects of Ethics Code: Industry and HCPs relationship; Products and Interactions.
- 5 inquiries have been resolved related ethics code application. No allegations at this time.



COMMUNICATION- COVID 19

New and up coming regulation related COVID 19 crisis.

Affiliate companies found daily reports extremely valued add to implement new regulation and internal control as required.



COMPLIANCE ENVIROMENT

- Focus on Ethics programs
- Transfer of value reports
- Investigations on going due to overcosts and other corruption issues increaaed during pandemic time.



CODE OF ETHICS JOURNEY

Ethics Code release
project kick off.

Neurobusiness
communication
strategy

Socialization: 5 cities,
more than 150 Indirect
channels ; Distributors
replicated this
conference in their
2020 Kick off meeting.

Ethics Code Launch
and certification ;
available at ANDI
website : As of today
more than **30**
companies and **1667**
individuals have been
certified.

CODE OF ETHICS SOCIALIZATION AND TRAINING



Invitación Especial

TALLER
Rentabilidad, sostenibilidad y cerebro

Código de ética dispositivos médicos

Bucaramanga
1 Octubre
Seccional ANDI Santander
Km. 2 Anillo Vial Ecoparque Empresarial Natura, Torre 1 - Oficina 309
8:00 am - 12:00 m

Cali
18 Octubre
Seccional ANDI Valle del Cauca
Calle 15 # 36-100, Autopista Cali - Yumbo (Auditorio ANDI)
9:00 am - 1:00 m

Cartagena
23 de Octubre
Centro de Convenciones Cartagena Getsemani, Calle 24 # 8A-544, Salón Pegasus
2:00 pm - 6:00 pm

Medellín
8 Noviembre
Seccional ANDI Antioquia
Carrera 439 # 1-50, San Fernando Plaza, Torre 1, Piso 9
9:00 am - 1:00 m

Bogotá
14 Noviembre
Federación de Cafeteros/Auditorio
Calle 73 # 8 - 13, Auditorio Torre C
9:00 am - 1:00 m

ANDI
Cámara de Dispositivos Médicos e Insumos para la Salud



we are
DRIVEN

PRINCIPAL CONCLUSIONS FOR THE ACTION PLAN

- It is very valuable that Colombia and the other countries of the Coalition have worked constantly to achieve an alignment with the Bogotá Principles in a visible and tangible way (Integrity, Independence, Transparency, Legitimate Interest, Accountability and Excellence).
- In times of Pandemia, strengthen the messages in favor of the Good Business Practices between the Government and the Private sector through public-private meetings (avoid Corruption and the opportunism of the New providers).
- Align concepts between the different codes of ethics, establishing a criteria unification schedule.
- maintain a scoreboard as the most valuable and tangible thing Advamed has in order to follow up on initiatives



COMMITMENTS AND CONCLUSIONS

- Make our ethical commitment visible with the government
- Advance through the training and certification process of the Code of Ethics, looking for increasing the companies engaged with the ethic's code
- Extend to stakeholders (scientific societies, health professionals and non-affiliates - companies and distributors) good practices and business ethics
- promote and seek that companies committed to the Association to multiply the compliance message



Inter-American
**Coalition for
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MEDICAL TECHNOLOGY SECTOR

Concluding Remarks from Coalition Executive Committee Members



Ana Riquelme
AMID (Mexico)



Claudia Freyre
AMID (Mexico)



Inter-American
**Coalition for
Business Ethics**

MEDICAL TECHNOLOGY SECTOR

Concluding Remarks from Coalition Executive Committee Members



Nancy Travis

AdvaMed (USA)



Inter-American
**Coalition for
Business Ethics**

MEDICAL TECHNOLOGY SECTOR

Summarize Coalition Meeting Outcomes



Inter-American
Coalition for
Business Ethics

MEDICAL TECHNOLOGY SECTOR

Planning for the 8th Inter-American Coalition Meeting and AdvaMed Digital MedTech Conference