2019 SUMMARY REPORT ON CODE OF ETHICS
IMPLEMENTATION BY MEDICAL TECHNOLOGY INDUSTRY ASSOCIATIONS

The Inter-American Coalition for Business Ethics in the Medical Technology Sector ("the Coalition") monitors code of ethics development and implementation by member medical technology industry associations across the Americas. These **14 national industry associations** (plus three regional/national alliances, one professional society, and one national ethics institute) collectively represent nearly **2,000 member enterprises**, of which nearly **1,400** are identified as SMEs. These enterprises constitute a majority of the firms that develop, manufacture, market, and/or distribute medical technologies (devices and diagnostic products) across the Americas, particularly within the ten countries where these organizations are based.[1]

This summary report overviews the second annual assessment of code of ethics implementation by Coalition medical technology industry associations. As such, it provides further data for the Coalition's capacity-building program to implement the Bogota Principles launched in 2017. **The Coalition is pleased to report that all national industry associations have adopted a code of ethics, the first time in the history of the region.** While this represents an important milestone, further progress is needed across all **four** key areas of effective code implementation: **(1) code governance**, **(2) code alignment**, **(3) enterprise adherence**, and **(4) external stakeholder engagement**. Coalition member industry associations continue to seek creative solutions to resolve the "non-member dilemma" – how to entice enterprises within the market (who are not association members) to adhere to the high-standards of the Bogota Principles.

CODE GOVERNANCE

Medical technology industry association codes of ethics are strong tools to disseminate and harmonize ethical business practices among many enterprises. However, they only serve as effective tools if robust code governance is in place. Through this assessment, the Coalition monitors several crucial areas to identify where such governance exists. The results across these areas are indicated in the following chart:

Assessment Area	"Yes" in 2019	"Yes" in 2018
Distributed the code to member companies within the last two years	**100% ↑**	93%
Internet version of the code is available in local language	**100%**	N/A
Resources to support code maintenance, promotion, and implementation	**93% ↑** **(Yes + Some)**	73% **(Yes + Some)**
Procedures to review the code and ensure it is up-to-date	**71% ↑**	67%
Provide one-on-one assistance to member companies seeking to align their business practices with the code	**71% ↑**	60%
Maintains a code complaint or violation procedure *(with routine use)*	**64% ↑ (20%)**	53% (20%)
Offer code of ethics training to member companies	**64% ↓**	67%
Planning to amend the code within the next 12 months	**57% ↑**	47%
Offer code of ethics training to third party enterprises	**43%**	N/A
Offer code of ethics training to individual sales representatives	**36%**	N/A

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[1] Coalition industry associations are based in the following countries: Argentina, Brazil, Canada, Chile, Colombia, Ecuador, Mexico, Peru, United States, and Venezuela. Many enterprises within these associations have operations in other countries.

CODE ALIGNMENT WITH THE BOGOTA PRINCIPLES

The Coalition is committed to ensuring that medical technology industry associations across the Americas achieve alignment with the Bogota Principles. Among the associations responding to the 2019 survey, **64%** report their code embraces all five fundamental principles of the Bogota Principles which is roughly unchanged from 2018. Among the same industry associations, **71%** report their code of ethics includes specific guidance to strengthen ethical relationships between medical device companies (such as manufacturers) and third party intermediaries (such as distributors). And **81%** also report that the association has sought to align its code or practices with the Bogota Principles Guidance for Ethical Third Party Sales and Marketing Intermediary (SMI) Relationships.

MEMBER ENTERPRISE IMPLEMENTATION

Assessing member enterprise implementation of a medical technology industry association's code of ethics is the most difficult component of the Coalition's monitoring activities. It remains a key goal of the Coalition to see all member industry associations report that a majority of their member enterprises adhere to the association code in their daily business practices. The data provided in this second annual assessment is dependent on estimates provided by each association. In 2019, **50%** report their code has performed "excellent" or "well" over the past year which is roughly unchanged from 2018. And **50%** report that a majority of their member enterprises have certified their compliance program with the association code of ethics, compared to 33% in 2018. A majority of the associations certify membership compliance with the code of ethics through member self-declaration.

The results of additional areas monitoring under member enterprise implementation include:

1. Association requirements on members to certify compliance with the code: **57%** require members to certify upon joining the association, **14%** require members to certify annually, and **29%** do not require members to certify.
2. Associations maintaining an active list of members who certify code compliance grew to **57%** from 40% in 2018.
3. Associations who receive notification when member enterprises conduct external validation or audits to measure compliance with the code: **Yes (7%) / No or Unknown (93%)**. This is unchanged from 2018.
4. Association Code Performance: **36%** Excellent, **14%** Well, **29%** Acceptable, **7%** Not Well, **14%** Unknown
5. Member Enterprise Implementation Rates: **43%** within 76-100%, **7%** within 51-75%, **21%** within 26-50%, **14%** within 25% or less, and **14%** are unsure of their member enterprise implementation rate.
6. At least **71%** do not have a mechanism for individual sales representatives to certify to the code.

EXTERNAL STAKEHOLDER ENGAGEMENT

Another fundamental goal of the Coalition is to heighten stakeholder collaboration across the Americas to strengthen ethical business practices between the medical technology industry (enterprises and associations) with relevant non-industry organizations (governments, healthcare professional groups, health providers, etc.) to promote sector development / innovation as well as to improve patient care. This assessment measures how Coalition member industry associations are undertaking such efforts. To start, **57%** of the industry associations have reported distributing their code of ethics to non-member organizations within the past year, including healthcare professionals, third parties, patients, and/or governments. This is relatively unchanged since 2018. And **29%** report their code of ethics trainings were made available to non-member organizations, down from 40% in 2018. At least **36%** are building awareness of their codes with non-members through formalized multi-stakeholder collaborations, such as consensus frameworks. And at least **71%** are interested in heightening external stakeholder engagement on the association's code of ethics.

COALITION MEMBERS

1. CADIEM (Argentina)	7. ABIIS (Canada)	13. ASEDIM (Ecuador)
2. ABIMO (Brazil)	8. MEDEC (Canada)	14. AMID (Mexico)
3. ABRAIDI (Brazil)	9. ADIMECH (Chile)	15. CCL-COMSALUD (Peru)
4. ABIMED (Brazil)	10. APIS (Chile)	16. AdvaMed (United States)
5. CBDL (Brazil)	11. SCDM (Chile)	17. AVEDEM (Venezuela)
6. Instituto Etica Saude – IES (Brazil)	12. ANDI – CDMIS (Colombia)	18/19. ALDIMED / ALADIV

SUCCESSES AND CHALLENGES

Associations were asked to describe the three great successes and the three greatest challenges they have faced in the adoption and/or implementation of a code of ethics. Below are a randomized collection of these responses:

Greatest Successes	Greatest Challenges
Creation of the Health Ethics Institute	Oversee if members are complying with the code
Compliance in Action Program	Helping members to adopt a compliance system, not only a code of ethics
Raise the number of members which have any compliance action	Expand the discussion about compliance to market players' anti-ethical practices and behaviors
Drafting of the new code	Huge variety of companies (size and business)
Alignment regarding educational grants in kind	Maturity of compliance program is very low
Some members are pharmaceutical companies	Maturity of healthcare organization regarding governance and compliance
Code fits local compliance landscape	Other distributors outside the association are not following compliance and have no ethical practices
More companies are joining the association to pursue our ethics compromise	Challenge of market dynamic in some practices, which involve different players/links in the commercial chain
Expanded compliance committee to supplement the code of conduct committee's activities	Challenge of having some country laws but light regulation to apply and just a few cases with sentence
Proof for the government that the association has a tool to promote ethical business practices	Challenge to the association of developing and then implementation a regulation
Achieved members' compliance requirements	Avoid giving gifts to the health authority
Development and adoption of code by members	Avoid the traffic of influences with health authority
Our members have not been reported for bribery	Avoid giving incentives to doctors
Our members do not have debts with the National Superintendence of Tax Administration	Due to voluntary nature of code related work, time and resources can be limited
Members have not been sanctioned by supervising agency for contracting with the state	Need to expand the code of conduct adoption to the associations SMEs as well as non-member companies
Work with key stakeholders	Promote our ethics commitment with government
Awareness and training for members by intranet communication and campaigns, two conferences, and three formal trainings	That with our new schemes of affiliation for another type of companies they are also interested in complying with our code and joining the association
Ending of direct sponsorship	Local companies join the association.
Inclusion of association code in RFPs and contracts	Building accessible training programs
All members have certified their code adherence	Global harmonization
HCPs have adapted to the end of direct sponsorships	Completing all aspects of association code revision
Cultural changing	Loss of one member for not subscribing to the code
Strides in global harmonization	Lack of experience in the ethics committee
Wide adoption & consistent re-certification	
Name recognition	
Implementation and development of the code	
Sharing the code with the Ministry of Health	
Sharing the code with private clinics associations	
Approval and commitment by all members	
Requirement of adoption/compliance for members	
Improve the level of business relationships	