

2018 SUMMARY REPORT ON CODE OF ETHICS IMPLEMENTATION BY COALITION 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 **15 national industry associations** (plus three regional/national alliances and one national ethics institute) collectively represent over **2,200 member enterprises**, of which over **1,500** are identified as SMEs. These enterprises constitute a majority of the firms that develop, manufacture, market, or distribute medical technologies (devices and diagnostic products) across the Americas, particularly within the ten countries where these associations are based.¹

This summary report overviews the first assessment of code of ethics implementation by Coalition medical technology industry associations. As such, it will provide a foundation of data for the Coalition’s capacity-building program to implement the Bogota Principles launched in 2017. From this outset of this program, the Coalition is pleased to report that **14** of the Coalition’s 15 national industry associations have adopted a code of ethics, with the 15th association code under development in Chile. While this represents an important step toward the achievement of the Coalition’s goal of universal code of ethics adoption by member industry associations, progress is also necessary 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 also seek creative solutions to resolve the “non-member dilemma” – how to entice those enterprises within the market (who are not association members) to adhere to the high-standards contained within 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” Response by Percentage / Total
Associations with current leadership committed to the code	100% (15/15)
Associations that distributed the code to all member companies within the last two years	93% (14/15)
Associations that distributed the code to member companies for input prior to adoption	80% (12/15)
Associations with sufficient resources to support code maintenance, promotion, and implementation	Yes (33%) + Some (40%) = 73% (11/15)
Associations who offer one or more code trainings to members	67% (10/15)
Associations with procedures in place to review the code and ensure it is up-to-date	67% (10/15) – 47% (7/15) plan to amend their code within the next year.
Associations that provide one-on-one assistance to members seeking to align their business practices with the code	60% (9/15)
Associations that have designated staff or a member company to oversee code maintenance, promotion, and implementation	53% (8/15)
Associations with a code complaint or violation procedure	53% (8/15) – Routine Use: 20% (3/15)

¹ Coalition industry associations are based in the following countries as of 8 April 2018: Argentina, Brazil, Canada, Chile, Colombia, Ecuador, Mexico, Peru, United States, and Venezuela.

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 2018 survey, **67% (10/15)** report their code embraces all five fundamental principles of the Bogota Principles and **53% (8/15)** report their code is intently aligned with all provisions of the Principles.

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 is a fundamental goal of the Coalition to see all member industry associations report by 2020 that a majority of their member enterprises adhere to the association code in their daily business practices. The data provided in this first assessment is dependent on estimates provided by each association. Among the associations responding to this first assessment, **53% (8/15)** report their code has performed "excellent" or "well" over the past year with **33% (5/15)** of those associations completing the survey reporting that a majority of their member enterprises adhere to the association's code in their daily practices. This will serve as an important baseline for the Coalition's capacity-building activities. **93% (14/15)** report that it would be very or moderately helpful to design and release an online business ethics training course to help their member enterprises adhere to the Bogota Principles.

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

1. Associations who require members to certify compliance with the code: **53% (8/15)**
2. Among those who do require members to certify compliance with the code, **43%** do so upon the member joining the association, **43%** do so on an annual basis, and **14%** do so on a less than annual basis.
3. Associations who maintain an active list of members who have certified code compliance: **40% (6/15)**
4. Associations who receive notification when member enterprises conduct external validation or audits to measure compliance with the code: **Yes (7% or 1/15) / No or Unknown (93% or 14/15)**
5. Association Code Performance: **27%** Excellent, **27%** Well, **33%** Acceptable, **13%** Unknown (**0%** Poor)
6. Member Enterprise Implementation Rates: **27% (4/15)** within 76-100%, **7% (1/15)** within 51-75%, **27% (4/15)** within 26-50%, **0%** within 25% or less. **40% (6/15)** are unsure of their association's member enterprise implementation rate.

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 will serve as the first step in measuring how Coalition member industry associations are already undertaking such efforts. To start, **53% (8/15)** of the industry associations responding to this survey have reported distributing their code of ethics to non-member organizations within the past year, including healthcare professionals, third parties, patients, and/or governments. And **40% (6/15)** report their code of ethics trainings were made available to non-member organizations. **61% (8/13)** also report that their code of ethics contains guidance for ethical relationships with third party intermediaries, which is likewise a component of the Bogota Principles.

COALITION MEMBER INDUSTRY GROUPS

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 (Regional)