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

Under AdvaMed's joint leadership with ALDIMED\(^1\) and the Business Ethics for APEC SMEs Initiative, principals from medical technology enterprises and associations, governments, and other health system stakeholders from across the Americas gathered in Lima, Peru 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 principles and a joint work plan through 2020.

The Coalition was launched at the 2017 Latin America Compliance Conference (21-22 February) in Bogota, Colombia, bringing together the 15 leading medical device and diagnostic industry bodies\(^2\) from across the Americas under the first joint arrangement to strengthen ethical business practices. This arrangement includes the development and implementation of high-standard principles ("The Bogotá Principles") to inform the alignment and implementation of industry codes of ethics across the region as well as to facilitate multi-stakeholder alignment and collaboration.

The Coalition has the following objectives through 2020:

1. Draft and adopt the Bogotá Principles for ethical business practices in the medical technology sector, applicable to industry and other relevant stakeholders [completed in February 2017];

2. Facilitate the adoption and implementation of codes of ethics – aligned with the Bogotá Principles – by every medical device manufacturer, including diagnostics, and distributor associations across the Americas;

3. Demonstrate the implementation of each industry association’s code of ethics by a majority of the member companies while facilitating adherence to the Coalition’s Bogotá Principles by other relevant stakeholders; and

4. Launch of national-level, multi-stakeholder partnerships between the medical technology industry and other interested parties with the common aim to implement the provisions of the Bogotá Principles.

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\(^1\) La Asociación Latinoamericana de Gremios de Dispositivos e Insumos Médicos (ALDIMED)

\(^2\) Coalition industry association members: CADIEM (Argentina), CBDL (Brazil), ABIIS (Brazil), ABIMED (Brazil), IES (Brazil), ABRAIDI (Brazil), ABIMO (Brazil), MEDEC (Canada), SCDM (Chile), ANDI-CDMIS (Colombia), ASEDIM (Ecuador), AMID (Mexico), CCL-COMSALUD (Peru), AdvaMed (United States), and AVEDEM (Venezuela).
The Inter-American Coalition for Business Ethics in the Medical Technology Sector and
The Americas Business Dialogue Recommendations

The Americas Business Dialogue (ABD) is an initiative driven by the private sector and facilitated by the Inter-American Development Bank (IDB) aimed at fostering policy dialogue among business and government leaders of the Western Hemisphere. The ABD has developed and is presenting policy recommendations for consideration by the heads of state attending the VIII Summit of the Americas in Lima, Peru. These recommendations reflect a consensus grounded in the ideas, discussions and technical expertise of more than 300 leading companies and major business associations from the Americas, including AdvaMed and ANDI.

Codes of Ethics

One of ABD’s recommendations under the theme of “strengthening transparency and integrity” is to encourage the private sector to adopt comprehensive integrity mechanisms, including codes of corporate conduct accompanied with effective implementation. The Inter-American Coalition for Business Ethics in the Medical Technology Sector strongly supports this recommendation.

ABD’s recommendations include a case study on Asia-Pacific Economic Cooperation (APEC) code of ethics implementation, where robust private sector collaboration with government has resulted in APEC principles for codes of ethics being extended to 26 device and diagnostic industry associations across 19 economies. These codes collectively represent higher standards of ethics being applied to nearly 13,000 companies, of which 11,000 are small and medium-sized enterprises.

The Coalition was built on this APEC model, having developed in 2017 high-standard principles (“The Bogotá Principles”) to inform the alignment and implementation of codes of ethics, applicable to industry (manufacturers and distributors).

The Bogotá Principles are also intended to facilitate multi-stakeholder partnerships between the medical technology industry and interested parties who share a desire for high standards for ethical interactions to ensure that medical decision-making is in the best interest of the patient. These parties may include governments, healthcare professionals, and other relevant stakeholders. The Coalition is envisioned as a public-private partnership and invites government participation.

Good Regulatory Practices

ABD also recommends implementation of mechanisms to ensure legitimate, transparent and technically sound regulations, and adoption of administrative simplification plans, as well as the development of a mechanism for private sector and inter-government coordination on dedicated regulatory cooperation projects that helps economies implement a shared set of Good Regulatory Practices (GRP), to develop competitive economies and support participatory and transparent democracies. The Coalition supports these recommendations.

The Coalition provides a concrete platform for good regulatory practices as the Bogotá Principles and the Coalition’s work plan through 2020 seek meaningful stakeholder engagement to strengthen ethical interactions in each economy’s healthcare ecosystem. This not only ensures that medical decision-making is in the best interest of the patient but also increases the region’s competitiveness.