

6th COALITION MEETING SUMMARY & ACTION ITEMS (24 JULY)

Following participant introductions and an antitrust reminder by local counsel, the Executive Committee members (ANDI, AMID, ABRAIDI, and AdvaMed) offered welcome remarks. Short presentations were concurrently provided by ANDI and AMID on code implementation and related items in Colombia and Mexico. ABRAIDI and AdvaMed focused remarks on the associations' expectations for the Coalition in 2019 and 2020, including improved code implementation and harmonization as well as new advances in fostering ethical third party sales and marketing intermediary relationships. ABRAIDI advised that the association is updating its code and developing a more effective strategy to quantify member adherence to the code. AdvaMed provided a short overview on the association's new code. CADIEM, as the host association in Argentina, provided a preview of the distributors' ethics training workshop on 25 July.

The technical secretariat provided participants with a brief historical overview of the Coalition's development as well as what to expect at the 7th Coalition meeting in Santiago de Chile on 9-10 September 2019. ADIMECH, APIS, and AdvaMed also confirmed they will co-host a distributors' ethics training workshop on 11 September in Santiago. It was also agreed that the Coalition's two meetings in 2020 will be held in Mexico City and alongside the Summit of the Americas (possibly Washington, DC or Miami) – dates to be confirmed.

The participants discussed the results of the 2019 Coalition survey on code of ethics implementation, including a detailed comparative assessment from 2018 on code alignment with the Bogotá Principles, member company adherence rates, and external stakeholder engagement on the code. **Members were collectively thrilled to announce that for the first time ever, all medical device industry associations in the Americas now have a code of ethics.** The technical secretariat also overviewed a consolidated summary of Coalition members' greatest successes and three greatest challenges indicated in the 2019 report. The most common success areas include: the adoption of new or more effective codes, strengthening ethics committees, improved member adherence, strengthened external stakeholder engagement, enhanced communication, and the ending of direct sponsorships. The most common challenge areas include: limited association resources and/or code maturity, limited member adherence, non-member dilemma, regulatory environment, and the variety of companies within an association's membership (i.e., manufacturers and third parties). Coalition members offered several inputs on the survey questions for 2020. Members agreed that the 2019 survey data demonstrates that more can be done to (A) build SME capacity in ethics and (B) heighten coordination with governments to strengthen code implementation. It was suggested that the Coalition and its members strengthen engagement with governments to promote positive approaches on ethical business conduct for all stakeholders. Members spoke at length about the need for innovative solutions to address the "non-member" dilemma: aligning ethical business practices between association member and non-member companies to create a level playing field.

A deep-dive presentation and discussion was then held on success indicators for effective code governance by industry associations. This session was well received by the Coalition members. As a core pillar to code of ethics implementation, effective code governance includes ensuring that association codes were adopted and remain sustained through collective action by the full membership. It also includes ensuring that codes are sufficiently resourced and positioned as living documents, routinely incorporated into all of the association's activities as well as updated on a routine basis. The presenters also discussed other governance areas, including diverse practices in code violation and enforcement.

Coalition members advocated for the creation of a compendium of examples from across the region on code violation, complaint, and enforcement procedures to better understand the variances across countries in the Americas. Coalition members agreed that they would like to see additional deep dive sessions like this in future meetings.

After a short break, the Coalition shifted the remaining focus of its session on strengthen ethical third party intermediary relationships, with a special emphasis on full realization of the Bogotá Principles. ABRAIDI led the discussion and initial presentation, including a brief assessment on the challenges facing medical device distributors in Brazil and other markets, such as timely payment of invoices to the distributor by healthcare providers and payers who utilize medical devices. It was agreed that greater focus on ethical third party intermediary relationship issues should remain a focus at the next Coalition meeting in Santiago as well as that the Coalition should identify 1-2 specific focus areas where it seeks to provide support and drive results (rather than a full range of issues).

Action Items:

1. Add question on estimated market share of the association's member firms vs. non-member firms.
2. Coalition members to prioritize resolving code implementation gaps indicated in the 2019 survey, including ensuring full alignment with the Bogotá Principles in future code revisions as well as expanded external stakeholder engagement on the code of ethics.
3. Coalition members to nominate 2-3 stakeholders per country to invite to future Coalition meetings.
4. Coalition members to identify 1-2 specific actions, in addition to member training, by 2020 that can be taken to shape a more favorable ethical business environment.
5. The Coalition should consider preparing a document that includes recommendations for governments on partnering with industry to strengthen ethical business practices.
6. Coalition members have requested additional "deep dive" sessions in future meetings, similar to the presentation prepared on effective code governance. Other deep dive topics could include strengthening member adherence and addressing the non-member dilemma as well as best practices to engage external stakeholders on the code.
7. The Coalition should also consider preparing a compendium of different code compliant and enforcement mechanisms across the region.