



2017 APEC Business Ethics for SMEs Forum

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Advancing Code of Ethics Implementation Course A – Internal considerations module Case Study 2

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Facilitators' Notes

This case study is aimed at economies where the association has implemented a Code of Practice, consistent with the Mexico City Principles, which has been generally adopted by member companies, but there is variability in the stage of internal implementation between different companies. How can the industry association, the fictitious Pharmaceutical Association of Malicuria Inc. (PAMI), assist and encourage member companies in their internal adoption and implementation of the Code?

Value proposition

Biopharmaceutical industry association codes of ethics are strong tools to disseminate and harmonize ethical practices among many enterprises. However, they only serve as effective tools if robust code governance is in place. Based on the statistics from 2016 APEC ethics survey (33 of the 50 with codes or commitments) indicate that most have a valid governance structure and have been undertaking improvement over the past year. Of note, 100% indicate that their current leadership is committed to the code; 94% indicate that there are the designated staff to oversee code maintenance, promotion and implementation; 85% associations have code compliance or violation procedures.

1. What activities could Bob's Committee develop and recommend to PAMI Member companies to enhance their Code compliance?
 - To demonstrate Code compliance, could you work with companies to establish the key components of a compliance program internally, such as:
 1. Written Policies & Procedures
 2. Designated Compliance Officer and Committee
 3. Effective Training and Education
 4. Clear lines of Communication and reporting
 5. Auditing and Monitoring
 6. Enforcement and Disciplinary Actions
 7. Response to Detected Problems & Corrective Actions



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- Develop a model framework for a Code implementation program, working with member companies who are more advanced, and share this with member companies who need more assistance. The collective “good” of demonstrating a high level of compliance across the industry should outweigh the competitive desire to keep good programs to themselves.
2. How to measure whether member companies have adopted the PAMI Code in their business?
- Set up an audit team reporting to the Board of the Association with a regular audit cycle – at least once per year to identify the potential issues and correction mechanism.
 - Companies would complete a self-audit of their implementation of the PAMI Code within their business. Self-audit results could be kept confidential for each company but de-identified collective results could be reported to all members and an individual members’ results provided to them confidentially
 - Engage an independent auditor to audit companies on an annual or biennial basis (this could be expensive and time consuming and the value would need to be demonstrated)
 - PAMI may regularly initiate the benchmark analysis by the activities, e.g. entertainment, sponsorship, symposia and congresses. Set up the dedicated team in PAMI to collect the complaint letters to report the potential violation. Bring the benchmark analysis and the violation cases to the board meetings to align the compliance standard across the board members. Share the best practices and learning to all member companies.
3. What measures could be introduced to encourage companies to adopt and internalize the Code and/or to sanction companies who do not appropriately adopt the Code?

What would a sanction system by the industry association for non-compliance with the industry code look like? This is one framework:

- Concern Letter and response considered by an independent adjudication committee
- Available sanctions could include:
- Order to rectify and correct the measures taken (i.e. failure to rectify can result in a contractual penalty - submit the case to the regulatory authorities for their eventual measures)
 - Warning notice
 - Notification of violation to the parent company
 - Fine depending on the nature and the severity level of the violation
 - Reprimand: For the repeated violation, e.g. 3 violations within a calendar year or 24 months and these violations have each been established by a non-appealable decision
 - Suspension of association membership
 - Cease of association membership



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- Public announcement of violation to general media or to other companies that have signed up to the code
 - Forward the case for further examination by public regulatory authorities
4. What would be the process for getting all PAMI member companies to accept Committee's recommendations?

The Board needs to give its strong endorsement for the intervention processes/tools as mentioned above to be able to get all PAMI member companies aligned. Bob should add his efforts to convince the Board members as the starting point, e.g. sharing the value proposition (see above) with the Board members.