Medical Device Distributors' Ethics Portal
Draft Work Plan & Considerations

This Work Plan outlays the proposed structure for a virtual platform to support the widespread utilization of the "Global Distributor Capacity Building Toolkit" released at the 2018 APEC Business Ethics for SMEs Forum in Tokyo. The utilization of this virtual platform will serve as the core capacity-building activity to realize implementation of the Tokyo Action Agenda.[1]

The target audience for this Toolkit is small to medium-sized distributors and other third party sales and marketing intermediaries engaged by medical device companies that interact with health care professionals, government officials, or other stakeholders on their behalf.

The *Business Ethics for APEC SMEs Initiative* and AdvaMed are pleased to contribute expertise to develop this virtual platform. Over the past several months, these efforts have included refining the Tool Kit by organizing materials into a continuum of phased implementation, with increasing complexity.

Resources are segmented in accordance with the phases of maturity in a distributor's ethics program. This approach will guide distributors through the process of building an effective compliance program with the resources they need, when they need it, as follows:

Phase 1: Code Adoption
Materials/guidance for the company to create its own code of ethics in alignment with relevant industry association codes while also building the company's own compliance and training program.

Phase 2: Communication Tools
Materials/guidance for internal and external communication concerning the adoption process and adherence details of the company's code of ethics.

Phase 3: Template Policies
Materials/guidance for creating template policies/contracts concerning consultant agreements, meeting sign-in sheets, payment for booth space forms, and anti-trust disclosure language, among others

Phase 4: Working with Sub-Distributors
Materials/guidance similar to above while geared toward working with sub-distributors.

Phase 5: Sophistication of Procedures
Materials/guidance on sophisticated record keeping, expense claims, detailed Code provisions, etc.

The Initiative and AdvaMed are working on the content of Toolkit while addressing implementation and uptake by distributors and third party intermediaries by introducing the materials to industry associations. Feedback is sought on the approach, the materials posted to http://klprinciples.apec.org, and the process that will be pursued to ensure uptake by individual enterprises.

[1] Tokyo Action Agenda: http://klprinciples.apec.org/CMFiles/APECTokyoActionPlanRecommendations.pdf

11:15-12:15, 9 SEPTEMBER 2019: DISTRIBUTORS PERSPECTIVES AND CHALLENGES

The leaders of medical device distributor associations and companies will provide feedback on this work plan. Michelle Wagner will facilitate the discussion with panelists as well as open the discussion to participants to provide inputs. The association leaders providing feedback on the draft work plan, as well as other Forum participants, should consider the following questions:

- **Does this approach make sense? Are the five phases of the resources appropriately segmented? Would you make any adjustments or expand upon the kinds of materials that are already indicated?**
- **Who are the right users within SME distributors and third party intermediaries for these resources?**
- **What approaches should be considered in order for industry associations to routinely utilize this resource for the benefit of their member companies? What do associations need to make it work? The Tokyo Action Agenda calls upon industry associations to conduct annual training programs.**
- **The Tokyo Action Agenda calls for a third party intermediary certification model by 2021. How can this be achieved together?**