



## DRAFT WORK PLAN – REVISED 4 SEPTEMBER 2019

### APEC SME Leaders in Ethics and Integrity Program (“LEIP”) Biopharmaceutical Sector

#### INTRODUCTION AND OVERVIEW

Since 2012 the [Business Ethics for APEC SMEs Initiative](#) (“Initiative”) has provided capacity-building support for biopharmaceutical industry associations in the adoption of voluntary codes of ethics. These efforts have included seven regional workshops and dozens of localized events, extending training to nearly 2,000 individuals from every APEC member economy. As the region’s biopharmaceutical industry associations have achieved near-universal code adoption in accordance with the [APEC Mexico City Principles](#) (“Principles”), the Initiative is evolving to support these associations’ advance implementation of the Principles by their member companies, an overwhelming majority of which are SMEs. The [Nanjing Declaration](#) not only calls upon every biopharmaceutical industry association in the APEC region to adopt a code of ethics, but also calls upon each association to realize a member company adherence rate of at least 50 percent. APEC Ministers have reaffirmed this target since 2014.

In 2018, the Initiative tested and launched a virtual “[SME Guide to the APEC Mexico City Principles](#)” and “[Resource Toolkit](#)” to begin supporting biopharmaceutical industry associations strengthen member company adherence to their respective codes of ethics. Insights from the initial testing and launch of these virtual platforms indicated that the Initiative would realize the greatest success by offering a platform for the associations that supports a specific user within each member company, rather than a capacity-building solution for the entire enterprise. Expert feedback affirmed that providing a platform to SME leaders (for example, CEOs or GMs) – building their championship for ethical business conduct – is the greatest intervention the Initiative could undertake to strengthen member company adherence to high-standard ethical business conduct (sometimes referred to as “tone-at-the-top”). In addition to a platform that offers ethics training for SME leaders, the Initiative could offer advantages that otherwise might not be available to SMEs, such as a major international network of companies, associations, and stakeholders who are committed to strengthening ethical business conduct.

The proposed APEC SME Leaders in Ethics and Integrity Program (“LEIP”) is a multi-stage platform to equip the top leadership of SMEs in the sector with the right tools to implement an effective ethics and integrity program in alignment with the APEC Principles, while also including strong business case and communication components. During the program’s initial rollout, biopharmaceutical industry associations across the APEC region will identify SME leaders to pilot the platform. Participation will then be expanded. The complete program is envisaged in four stages, ultimately leading to the SME leaders’ certification and participation in an LEIP network:

- **Phase One, Invitation Selection**
- **Phase Two, Ethics and Integrity Assessment:** Once industry associations have identified the SME leaders for the program, those associations will send a survey link to SME leaders to complete an online assessment to verify their level of efforts to implement ethical business practices in their organization
- **Phase Three, LEIP Seminar:** SME leaders to participate in an in-person seminar that includes 1) the business case for ethics and integrity and 2) low-cost methods of creating a culture of integrity. Industry associations may support this by hosting the seminar
- **Phase Four, Networking Meeting and Certification:** A networking component will be included in the seminar to offer an opportunity for SME leaders to interact with peers and potential collaborators or customers they otherwise may not have an opportunity to meet. After completing the networking component, the SME CEO receives a verification / certification from the *Business Ethics for APEC SMEs Initiative*

- **Phase Five, Ongoing Updates and Verification / Certification Maintenance:** SME leaders will participate in a brief survey as well as continue to engage in online and in-person components of the platform as a condition of maintaining the verification / certification

## STAKEHOLDERS

Success of the program requires investment from several stakeholders in addition to the SME Leaders.

### A. Business Ethics for APEC SMEs Initiative (“Initiative”) in the Biopharmaceutical Sector

The Initiative plays a role in three major areas:

- Support in program development by associations: associations will require assistance, particularly in the initial stages of the program, in identifying useful case studies and identifying speakers, both in terms of substantive training and in terms of experienced SME Leaders who can provide real-world experience, with the idea that associations will eventually develop their own pool as CEOs complete the program. The Initiative can gather case studies, facilitate engagement with business schools with active business ethics programs, and provide lists of willing participants for the seminars.
- Ethics and integrity assessment: while associations will need to adapt their programs to the local circumstances, the Initiative should review those programs to be sure they meet baseline standards to ensure a level of quality that meets international standards.
- Certification: associations will make the determination of who has completed the program and therefore can be certified (or who has sufficient issues that decertification is necessary) but an Initiative (APEC) certification will certainly be more meaningful if it is region-wide, and it will also be more helpful to companies outside each individual country to have a centralized database where they can check independently whether a company is certified or not.

The Initiative will also gather and disseminate information from the metrics established by the program (which would be facilitated by maintaining the certifications, as they would not need to collect the data from the associations), in order to measure the success of the program specifically, and implementation of the Principles more generally.

### B. Biopharmaceutical Industry Associations

Associations will play a key role throughout the process, as local ownership and adaptation is critical to the success of the program. They will need to:

- Establish the LEIP and adapt to local circumstances and their own membership
- Host the LEIP Seminar and Networking Meeting
- Work with the Initiative to create standards and maintain Certification

Smaller associations may need significant support. It might be that the multinational corporations, governments, or others can identify particular associations with which they will partner to provide assistance directly to the associations to lighten the load. It is important that associations play a central role, not only because they are in the best position to ensure effectiveness of the program for their constituency and their geography, but because they will also benefit the most from an active, strong network of members with a clear commitment to transparency and ethics.

### C. Multinational Companies

While multinational companies' in-country general managers may be participants in the program, it is also important that multinational companies<sup>1</sup> more generally participate in the program in three ways:

- Support development of LEIP training materials in initial stages and in the seminars: While the hope is that after programs are established, experienced local CEOs will lead workshops and training on success stories and challenges, in the initial stages, the multinationals may be in the best position to assist in developing industry-specific case studies and to provide personal experience as part of the seminar.
- Participation in the networking meeting: This is perhaps the most critical engagement for the multinationals in the early stages. As the networking event is designed as not just an opportunity to share experiences directly in a relaxed environment and to create relationships for mutual advice and support, but also as an opportunity to generate business. For that to succeed, there will need to be access to and participation by senior individuals from the sales-side of the multinationals (and even better if they are from headquarters) who can make decisions about potential business partners and can share real-world experiences about ethics and integrity and their value. Attendees should not just be compliance personnel, who might not be viewed as able to relate to the situation of a CEO and who could be viewed as providing substantially less of a benefit to the network if they do not make purchasing or vendor decisions.
- Placing meaning and emphasis on certification in choosing partners: For the certification to actually serve as an incentive, it needs to have actual value in securing clients and customers. While not all of the companies participating will be looking to multinational companies for business, if multinationals value it, other stakeholders, such as hospitals, physicians, and governments are more likely to value it, or at least to engage to learn more.

### D. Governments

While governments will not necessarily play a role in the initial stages, governments might have recommended speakers for the training sessions. Governments can play an important role as the program is implemented more broadly by also placing meaning on the certification process, and potentially including certification as an advantage in bidding for public tenders or for other benefits as appropriate to each legal system.

## APPENDIX I: THE APEC SME LEADERS IN ETHICS AND INTEGRITY PROGRAM

### A. Phase One: Invitation Selection

In order to establish a strong base to the program that can be added to over time, it is recommended that biopharmaceutical associations select a lead from their SME membership to serve as the LEIP "ambassador." Ambassadors are those who serve as leaders in the ethics and integrity and a proven track record in engagement on their Code of Ethics. Once this group of ambassadors is established, then wider participation can be expanded. The identification of ambassadors does not need to be a CEO – in most cases it will not be, but should be someone senior. The online portal should ask for that persons' name, title, and reporting chain (to ensure they are sufficiently senior), as well as contact information, as the invitation for Phase Two will go to that executive as well as to the CEO.

The invitation (which can be issued in the form that best suits the association membership) should include a complete description of the program and its benefits, an overview of the business case for ethics and integrity, and

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<sup>1</sup> It should be noted that participation in the network and the seminar has advantages for the multinationals as well – it is a fast and easy way to identify those partners in particular countries who have a commitment to ethics and integrity, and to meet the heads of the organizations to learn more and determine if they might be good partners in a relaxed environment.

potentially could include some points for presentation to the CEO to encourage participation. If there are customers or other stakeholders who have already agreed to participate in the seminar or networking event, they could be specifically identified to incentivize participation.

## **B. Phase Two: Ethics and Integrity Assessment**

Once SME leaders have been selected to be invited into the program, they should demonstrate the actions they have already taken to adopt a baseline ethics and integrity program via an online portal from the biopharmaceutical industry associations. Their company employees can self-certify that those elements exist and provide links (for example, to a corporate code of ethics) where appropriate. A few examples include:

- Does your company have a publicly-available code of ethics specific to the company?
- Does your company have a publicly-available mechanism to report concerns?
- Have employees in sales positions have received ethics and integrity training?
- Have senior executives have engaged in regular messaging regarding the importance of ethics and integrity?

Associations may want to provide examples for the company on the importance of tone at the top and executive messaging by asking for examples of executive messaging on ethics and integrity that the company has used in the past, or if they have not done any executive messaging, to prompt them to do so.

It might be of assistance in this phase to direct participants to the Principles and “[Resource Toolkit](#)” if they do not already have a program established.

Once the submission via the online portal has been approved by the association, the company would provide the executive identified with the details of the next LEIP Seminar and an invitation for the identified SME leader / CEO of that company to participate. Associations may also wish at this point (if not done in the invitation, or to reinforce what was in the invitation) to provide the executive with talking points to encourage the CEO to participate in the program, emphasizing the benefit of the program to the company overall.

## **C. Phase Three: LEIP Seminar**

While this element of the program may go by a variety of names (a seminar, conference, or convocation) depending on the circumstances, in essence it is a training session designed to answer the two key questions that the experts with whom we consulted identified as the two barriers to active advocacy for ethics and integrity: (1) **Why** should I and my company invest the time and resources in an ethics and integrity program? (2) **How** do I implement such a program in an efficient and cost-effective way that limits any negative impact on my business?

In designing the program, there was discussion of whether it should be a requirement that the LEIP attendees participate in person, or whether it should be available via webinar or other on-line system to facilitate participation by smaller companies and by those that might be remote from urban centers where the seminar would likely be held. Although there are significant cost savings both to participants and to the associations for online training, studies show that such cost savings generally are ephemeral due to the difference in the impact of the training. Ultimately, the online options were rejected, as discussed further in Appendix 1.

### **Morning Seminar – Why? The Business Case for Ethics and Integrity**

**Goal:** For SME leaders to gain insight from real-world experience with the various aspects of the business case for ethics and integrity – the benefits of such a program for 1) employees; 2) investors; 3) customers / clients; 4) public perception; 5) regulators.

**Format:** Case studies (potentially from leading business schools in the region such as Ateneo de Manila University in the Philippines)

- 1. Employees:** Companies that have a strong, value-based corporate culture backed at the highest levels of the company show improved employee engagement, increased productivity, and significantly reduced

employee turnover and all the attendant costs. Moreover, a public reputation for its core values attracts like-minded employees, making them more amenable to an overall business approach based on ethics and integrity and reducing the need for oversight. All of this reduces costs and increases profits.

**2. The Customers/Clients:** This panel is where the engagement of other stakeholders in the process will be the most critical. The audience will determine the appropriate panelists, whether multinational companies, hospitals or physicians/pharmacist organizations, or large drugstore chains. This should be individuals actively engaged in deciding from whom their organization buys or with which companies they such factors as their own due diligence requirements, the reduction in their overhead costs because less oversight is required, their own concerns about managing their reputation.

**3. Public Perception:** In many jurisdictions, the public perception of biopharmaceutical companies is poor, for a variety of reasons. In many regards they are viewed as unethical – whether it is pricing, quality, availability, or other reasons. Improved public perception of not just a particular company but of the industry in general has myriad benefits, including reducing the number of customer complaints, attracting talented employees, and similar benefits. This can also impact things like investment - ethical investment funds provide a good case study here to highlight that companies with ethical business cultures outperformed other companies in market value added, economic value added, and price/earnings ratio.

**4. Regulators/Enforcement:** Participants will certainly be aware that ethical companies are less likely to face regulatory or enforcement actions or investigations (primarily because they are less likely to violate those rules, but also because compliance defenses may be available to them that otherwise would not be). Where there is a good relationship with enforcement authorities, companies can seek their assistance in weeding out bad actors, or in pursuing employees who violate internal codes of conduct.

#### **Afternoon workshop – How? Low-Cost Methods of Creating a Culture of Integrity**

**Goal:** For SME leaders and CEOs to actively engage with their peers on low cost methods of creating a culture of integrity. These sessions should focus on scalability, and in particular at the things that CEOs can do that have a major impact with minimum time and resource commitments.

**Format:** Workshops, with participants making suggestions and strategies rather than a presentation

This is the session that will change year on year and become one of the key elements for SME leaders and CEOs to attend each year for exposure to new and emerging trends, and to share their own experience with their fellow leaders in small groups. This workshop is envisioned to include:

**1. Elements of a Successful Ethics and Compliance Program:** What are the building blocks of a successful ethics and integrity program, and how does a company manage its program to advance a culture of compliance? Existing compliance program overviews – such as the OECD Good Practice Guidance on Internal Controls, Ethics, and Compliance or the World Bank Group Integrity Compliance Guidelines could form the basis for this session, perhaps provided to the participants for review prior to the session to facilitate discussion of how to scale each of those elements to function within an SME.

**2. Designing an Executive Messaging Strategy:** A critical element of tone at the top is regular messaging from senior executives on the importance of ethics and integrity. This is important not just to send the appropriate message, but to ensure that all employees know that it goes to the very top of the organization and if they have management that is acting unethically or improperly, they have recourse higher in the organization. For each company structure and environment, the most effective way to regularly communicate the CEOs strong commitment to ethics and integrity and reinforce the corporate program will vary. Participants should be given examples of successful messages, as well as successful

methods for delivery in similar companies, and then asked to work in small groups to come up with their own message and at least two methods for communicating that message to their employees.

**3. Low-Cost Incentives for Ethics and Integrity:** While not all incentives – low cost or otherwise – involve the CEO, in many companies, particularly in Asia and particularly in SMEs, an incentive that involves meeting with the CEO or receiving public praise from the CEO can reap enormous benefits at no cost but a small amount of the CEO’s time, such as innovation awards that include a lunch or event with the CEO, a paid day off for being an ethics champion, such as resisting a bribe demand from a customer, or similar programs. After being provided with examples, the CEOs should break into small groups – different groups from the prior session, to spread engagement – and generate a list of low-cost things that their employees would value that could be used as incentives to promote ethics and integrity, and to generate a list of behaviors that they would want to reward (innovation, adherence to ethics in the face of challenges, etc.).

**4. Decision-Making Dilemmas – SME Leader and CEO Challenges:** What kind of dilemmas can CEOs expect to face, and how do they address them in a transparent and ethical fashion? What should they be considering in responding to those issues? Topics include conflicts of interest, misconduct in engagement with customers, and reputational issues. For this session, each group could be provided with a different kind of challenge to address, design an approach to decision-making and apply it, and then share with the broader group for discussion.

**5. Experience Panel – What Works and What Doesn’t:** This panel will highlight detailed experiences and best practices from SME leaders who have made the decision to commit their companies to ethics and integrity and where appropriate, how much it actually cost in terms of time, money, and productivity.

#### **D. Phase Four: Networking Meeting and Certification**

The networking meeting and certification process are the primary incentives for SME Leaders to participate in the LEIP Seminar. They also provide a simple way to collect metrics on participation and successful completion of the course and open a broader forum for dialogue about ethics and integrity generally at a time when the lessons and the questions are fresh in the minds of all participants.

##### **1. Networking Event**

The networking event is one of the greatest incentives to participation (particularly in-person) for the CEOs, and until such time as it is clear that the certification has meaning and benefits, it may be the only incentive. This networking event will offer access to sales opportunities only available to this select group.

##### **2. Certification**

Associations should establish the criteria for certification – at a minimum that the company has completed Phase One - Three. Those companies that are certified should be permitted to promote the certification in marketing materials, such as through the use of an approved and secure logo indicating “APEC SME Leaders in Ethics and Integrity Program Certified,” that is uniform across all APEC economies.

Certification should be maintained to be independently verified by the Initiative – most easily by maintaining a page on the Initiative website. Certifications will be updated on a three year basis.

Associations should determine on a case by case basis if certification should be revoked. For example, any company convicted of a bribery offense should lose its certification or be ineligible to receive it for some period of time or until certain personnel are replaced. What might be more challenging is to establish a mechanism by which customers or governments could challenge a company’s certification based on misconduct or unethical behavior short of conviction. What these criteria should be merits further discussion.

## **E. Phase Five: Ongoing Updates and Certification Maintenance**

For the program to truly be effective, it cannot be a “one and done” architecture. Once the program is completed, in order to maintain certification there should be an ongoing demonstration that the commitment remains firm. It also provides an opportunity to maintain ongoing metrics of the effectiveness of the program – not just how many SME Leaders / CEOs participate and complete the program, but how many continue the commitment. Further, continued participation allows for more substantive, rather than just numerical, feedback on successes and challenges.

A three-year cycle of recertification (the same recommended cycle for periodic risk assessments for smaller enterprises under multiple international standards) is recommended. The recertification process should include two parts:

### **1. Questionnaire**

A questionnaire should be sent to currently-certified SME Leaders at least three months in advance of the LEIP Seminar to secure feedback on the program. The questionnaire should include:

- Overall feedback on the success of the ethics and integrity program within the company;
- Information regarding at least one success and at least one challenge for the SME Leadership in promoting a culture of ethics and integrity within the company;
- Examples of executive messaging on ethics and integrity in the preceding quarter;
- An updated version of the company’s program, including date of last revision; and
- Any comments or thoughts on workshops or sessions that might be useful for the LEIP Seminar.

### **2. LEIP Seminar**

The SME Leader should participate in the afternoon session of the Seminar. The questionnaires can also be used by the association to identify SME Leaders whose participation on the experience panel might be particularly valuable for peers – whether for best practices or for challenges.

## **Next Steps**

<b>Recommendations for Biopharmaceutical Industry Associations</b>
<ul style="list-style-type: none"><li>• By 2020, at least two biopharmaceutical industry associations should pilot each stage and the Initiative should host a webpage with the names of those SMEs who have undertaken the APEC SME LEIP.</li><li>• By 2021, all biopharmaceutical industry associations should track whether they have hosted a LEIP Seminar, and track progress of the number of executives completing the program.</li><li>• By 2022, at least four of the biopharmaceutical industry associations should indicate involvement in APEC SME LEIP program.</li></ul>