



Business Ethics for APEC SMEs Initiative: **Vision 2025**

Promoting Ethical Environments in the Medical Device and Biopharmaceutical Sectors

1. We, representatives from patients and patient organizations, healthcare providers and professional organizations, health ministries and regulatory agencies, SME and economic ministries, anti-corruption authorities, medical device and biopharmaceutical industry organizations, researchers and academia, manufacturers, third party sales and marketing intermediaries (such as distributors, wholesalers, and sales agents) from across the APEC region, convened virtually to chart the course of our joint Vision 2025 for the *Business Ethics for APEC SMEs Initiative*. In doing so, we commit to solidify and grow the world's largest public-private, multi-sectoral partnership in the advancement of business ethics in the medical device and biopharmaceutical sectors through expanded best practices-setting, capacity-building, and active monitoring and evaluation of results. We commit to take these actions while recognizing this initiative's important role in reinforcing business ethics and integrity amidst the COVID-19 pandemic and to support the recovery of APEC member economies. These actions help to ensure a culture that upholds patient trust and where SMEs can sustainably operate and innovate across the region.
2. We make these commitments with the knowledge that since the 2014 APEC Nanjing Declaration¹ nearly two thousand stakeholders have engaged in this public-private partnership from every APEC economy. This has resulted in code of ethics adoption by 50 medical device and biopharmaceutical industry organizations, more than double the total number of codes in existence prior to these efforts.² Codes of ethics are also in place across ten APEC economies where they previously did not exist.
3. We reaffirm our support for the APEC Kuala Lumpur Principles for Voluntary Codes of Ethics in the Medical Device Sector³ and the APEC Mexico City Principles for Voluntary Codes of Ethics in the Biopharmaceutical Sector.⁴ These principles represent high standards in ethical practices for each sector and strengthen the ability of SMEs to sustainably operate and engage in cross-border trade. Ethical interactions between industry and healthcare professionals can help to provide healthcare providers and their patients with the information they need to make informed healthcare decisions.
4. We extend our appreciation to APEC Economic Leaders, APEC Ministers, APEC Ministers Responsible for Trade (MRT), APEC SME Ministers, and the APEC Business Advisory Council (ABAC) for their support of this initiative and efforts to strengthen ethical business practices for the benefit of SMEs. We recall their numerous statements encouraging progress while guiding member economies to support the local adoption and implementation of codes of ethics aligned with APEC principles.
5. We extend our appreciation to the APEC SME Working Group for a decade of leadership in overseeing the *Business Ethics for APEC SMEs Initiative*, the world's largest public-private partnership to strengthen ethical business practices in select sectors crucial to SMEs, APEC economies, and their people. As a result of their guidance and support, more than 13,000 SMEs are benefitting from improved capacity and a level playing field through the implementation of ethical business practices.
6. We recognize that the APEC region's health systems and stakeholders are extraordinarily diverse. As such, we understand they face varied opportunities and obstacles in their common mission to improve patient outcomes. We acknowledge that ethical collaboration among key stakeholders, including SMEs, and mutual trust built on high standards of integrity within our health systems can improve patient outcomes. As such, we celebrate the launch

¹ APEC Nanjing Declaration (2014-2020): http://mddb.apec.org/Documents/2014/MM/SMEMM/14_smemm_020a.pdf

² 2019 Reports on Code of Ethics Implementation by APEC Industry Associations: <http://mcprinciples.apec.org>

³ APEC Kuala Lumpur Principles: http://mddb.apec.org/Documents/2011/SOM/CSOM/11_csom_023.pdf

⁴ APEC Mexico City Principles: http://mddb.apec.org/Documents/2011/SOM/CSOM/11_csom_021.pdf



of consensus frameworks by hundreds of stakeholders across the APEC region. We welcome these voluntary, customizable, and inclusive platforms. They enable stakeholder collaboration to strengthen ethical business conduct, build trust, and promote accountability. In this context, we reaffirm the Nusa Dua Statement⁵ establishing that each stakeholder has a unique and important role to promote ethical healthcare environments.

7. We recall that it is often necessary for researchers and manufacturers to contract with third party sales and marketing intermediaries (SMIs) to support their activities. SMIs serve an integral role in these sectors and a majority of them are SMEs that contribute to employment and commercial activity in the APEC region. As such, we reaffirm APEC Guidance for Ethical Third Party Intermediary Relationships in the Medical Device Sector⁶ (Guidance) which states that companies and SMIs should develop and adhere to codes and compliance programs that embrace The APEC Kuala Lumpur Principles and include the following elements: written anti-bribery policy/procedure; risk assessment; diligence program; written contract; training and education; monitor/audit; and, appropriate corrective action. We embrace the Tokyo Action Agenda⁷ and have included its recommendations for Guidance implementation into this Roadmap.

8. Recognizing our shared achievements and continued commitment to advancing the best interest and health of patients, we agree on a collective vision for the future of this initiative with recognition that there is more to be done to achieve regional alignment and implementation in ethical business practices for both sectors. We declare our intention to APEC SME Ministers, APEC Ministers and APEC Leaders to achieve the following goals and call upon APEC economies and stakeholders to undertake the following actions to achieve them, respecting the diversity of healthcare systems:

VISION	ACTIONS
<p><i>Adoption of consensus frameworks in each APEC economy by 2023 and implementation by 2025.</i></p>	<ul style="list-style-type: none"> • Each APEC economy take steps to form a consensus framework by 2023, using the 2018 Guide to Facilitate Multi-Stakeholder Ethical Collaborations⁸ as a voluntary resource. • Each APEC economy implements a consensus framework by 2025, using strategies outlined in the 2018 Guide to Facilitate Multi-Stakeholder Ethical Collaborations as a voluntary resource. • Monitor adoption and implementation of consensus frameworks in each APEC economy with defined performance indicators. This includes a routine meeting schedule, organized governance process, transparent procedures, and an annual APEC status report.

⁵ Nusa Dua (Bali) Statement: http://mddb.apec.org/Documents/2013/SMEWG/HLM/13_smewg37_hlm_statement.doc

⁶ APEC Guidance for Ethical Third Party Intermediary Relationships in the Medical Device Sector: http://mddb.apec.org/Documents/2017/MM/SMEMM/17_smemm_016.pdf

⁷ Tokyo Action Agenda to Promote Ethical Third Party Intermediary Relationships in the Medical Device Sector: http://mddb.apec.org/Documents/2018/SMEWG/SMEWG47/18_smewg47_016.pdf

⁸ Guide to Facilitate Multi-Stakeholder Ethical Collaborations (2018 Version): http://mddb.apec.org/Documents/2018/SMEWG/SMEWG47/18_smewg47_014.p



<p><i>Ensure the APEC Principles are updated to reflect the highest standards of ethical business practices by 2021</i></p>	<ul style="list-style-type: none">• Convene an expert working group for each sector, comprised of multi-stakeholder representatives, by 2021 to review the APEC Kuala Lumpur Principles and the APEC Mexico City Principles and to provide recommended updates to reflect the latest high standards of ethical business conduct.• The review and recommended updates to the APEC Principles, as well as future actions taken by the Initiative, should consider emerging technologies and innovations in these sectors as well as challenge the role and responsibilities of relevant stakeholders in new ethical business dilemmas.• Updates to the APEC Principles for either sector should be reflected in industry code adoption and implementation activities undertaken by the <i>Business Ethics for APEC SMEs Initiative</i>, including capacity-building programs and annual monitoring.
<p><i>Measure the impact of ethical business practices in the medical device and biopharmaceutical sectors</i></p>	<ul style="list-style-type: none">• Complete one or more impact assessments, literature reviews, or experiments by 2022 measuring the impact of ethical business practices in the medical device and biopharmaceutical sectors. This effort may cover the economic, business (especially SMEs), health, and/or innovation benefits of ethical business practice implementation aligned with the APEC Principles. Consider completing this effort in partnership with academic institutions and/or international organizations.
<p><i>For the Medical Device and Biopharmaceutical Industry: Code of ethics adoption by all medical device and biopharmaceutical industry organizations by 2021.</i></p>	<ul style="list-style-type: none">• Convene a multi-stakeholder, dual-sector team to outreach to and provide active support for industry organizations that have not yet adopted a code of ethics.• The APEC Biopharmaceutical Working Group on Ethics may also advise on strategies to achieve this goal, including a communications strategy.• Complete annual survey and report on code of ethics adoption by medical device and biopharmaceutical industry organizations and report the results to the APEC SME Working Group for review and comment. Transmit the results to governments and the public, as appropriate, to highlight where code adoption successes and gaps may remain.



For the Medical Device and Biopharmaceutical Industry: Code of ethics implementation by all medical device and biopharmaceutical industry organizations by 2025, realized through member enterprise adherence rates of 100% for every industry association code.

- Convene a multi-stakeholder expert team to outreach to and provide active support for industry organizations seeking to strengthen code of ethics implementation, including governance, alignment with the APEC Principles, member enterprise adherence, and external stakeholder engagement.
- Complete annual survey and report on code of ethics implementation by medical device and biopharmaceutical industry organizations and report the results to the APEC SME Working Group for review and comment. Transmit the results to governments and the public, as appropriate, to highlight where code implementation successes and gaps may remain.
- Provide a code of ethics compendium and toolkit for each sector to help companies, including SMEs, implement high standard ethical business practices. The compendiums may contain a website link to each industry organization's code of ethics as well as an annual statement from each industry organization affirming their code of ethics aligns with the APEC Principles.
- APEC SME Leaders in Ethics and Integrity Program (LEIP)
 - Convene APEC SME LEIP seminars in partnership with industry organizations across a majority of APEC economies by 2025. APEC SME LEIP supports member enterprise adherence to industry organization codes of ethics by fostering “tone-at-the-top” by the leaders of individual SMEs, providing them with dedicated capacity-building and an international network.
 - Pilot two APEC SME LEIP seminars in 2020, assessing the modules and effectiveness through user feedback and industry organization assessment on implementation needs.
 - Develop APEC SME LEIP Masterclass, including such materials as business leader testimonials, case studies, and decision-making frameworks.
- Collect examples of code certification, complaint proceedings, or other enforcement mechanisms by APEC medical device and biopharmaceutical industry organizations. The Overseer may showcase these examples to other interested industry groups in support of their code implementation activities and efforts to realize the goal of 100% member enterprise adherence.
- Once the examples of code certification have been collected, the Overseer may convene an expert working group to pilot the creation of a code certification resource.



<p><i>For the Medical Device Industry:</i> Realize the goals in the Tokyo Action Agenda to Promote Ethical Third Party Intermediary Relationships in the Medical Device Sector.</p>	<p>Double the number of industry organizations that have implemented codes of ethics or issued recommendations consistent with APEC Guidance for Ethical Third Party Intermediary Relationships in the Medical Device Sector</p> <ul style="list-style-type: none">• By 2021, double the number of APEC medical device industry organizations – from 13 to 26 – that have implemented a code of ethics that contains the provisions of the Guidance (or have issued recommendations consistent with the Guidance). <p>Double the number of industry organizations with annual Third Party SMI training by 2021</p> <ul style="list-style-type: none">• By 2021, double the number of APEC medical device industry organizations – from 9 to 18 – that hold at least one annual Third Party SMI training activity. <p>Develop an online Third Party SMI training and certification program</p> <ul style="list-style-type: none">• By 2020, pilot a Third Party SMI training program in at least two economies to reach over 1,000 distributors.• By 2021, assess the results of the pilot program, incorporate key learnings, and build a certification mechanism for all APEC member economies.
<p><i>For the Biopharmaceutical Industry:</i> Develop guidance on ethical third party intermediary relationships in the biopharmaceutical sector.</p>	<ul style="list-style-type: none">• Convene an expert working group, comprised of multi-stakeholder representatives, by 2021 to prepare voluntary APEC guidance for ethical third party intermediary relationships in the biopharmaceutical sector.• The Overseer may assess the recommendations and submit for APEC SME Working Group review and, as appropriate, APEC SME Minister’s recognition. The Overseer may also assess the recommendations and submit for review, as appropriate, to other APEC working groups to facilitate cross-fora collaboration.• Should such guidance be finalized, its recommendations should be reflected in industry code implementation activities, building upon the high standards of the APEC Principles.



<p>For Patient Organizations: <i>Promote strategies to encourage ethical business conduct.</i></p>	<ul style="list-style-type: none">• By 2020, convene a task force of patient organization leaders to provide routine guidance on strategies to encourage ethical business conduct, including the adoption and implementation of consensus frameworks in each APEC economy.• By 2021, the task force should prepare an article for publication on the role of patients and patient organizations to encourage ethical business conduct in health systems, including the role of patients and patient organizations in building the capacity of SMEs to adhere to high standard ethical business practices.
<p>For Patient Organizations: <i>Develop guidance on patient and patient organization interactions with industry.</i></p>	<ul style="list-style-type: none">• Convene an expert working group, comprised of multi-stakeholder representatives, by 2021 to prepare voluntary APEC guidance on patient and patient organization interactions with industry, including SMEs, to reflect the latest high standards of ethical business conduct. These efforts may be combined with actions to modernize the APEC Principles.• The Overseer may assess the recommendations and submit for APEC SME Working Group review and, as appropriate, APEC SME Minister’s recognition. The Overseer may also assess the recommendations and submit for review, as appropriate, to other APEC working groups to facilitate cross-fora collaboration.• Should such guidance be finalized, its recommendations should be reflected in industry code implementation activities, building upon the high standards of the APEC Principles.
<p>For Healthcare Professionals (HCPs): <i>Promote strategies to encourage ethical business conduct.</i></p>	<ul style="list-style-type: none">• By 2021, convene a task force of HCP leaders to provide routine guidance on strategies to encourage evidence-based and ethical business conduct, including the adoption and implementation of consensus frameworks in each APEC economy.• By 2022, at least two APEC economies may pilot education curriculum based on the APEC Principles for dissemination to early career healthcare professionals.• By 2023, at least one HCP organization in each APEC economy will adopt a code of ethics that aligns with the prevailing ethical business standards set by the appropriate local professional authority and/or the APEC Kuala Lumpur Principles and the APEC Mexico City Principles.



<p><i>For Healthcare Professionals (HCPs):</i> Realize the goals in the Tokyo Action Agenda to Promote Ethical Third Party Intermediary Relationships in the Medical Device Sector.</p>	<ul style="list-style-type: none"> • HCP organizations to align codes of ethics, related policies and practices, and communications with the APEC Kuala Lumpur Principles and include an understanding of Third Party SMIs. Where local HCP codes are equivalent to, or more stringent than, the APEC Principles, these codes should be used. • By 2021, HCPs organizations to develop success metrics that advise the Initiative on improvements in HCP awareness of and/or code alignment with the APEC Kuala Lumpur Principles and the role of Third Party SMIs.
<p><i>For Governments:</i> Promote government strategies to encourage ethical business conduct in both sectors.</p>	<ul style="list-style-type: none"> • Bring together stakeholders, including patients and patient organizations, to encourage the adoption and implementation of consensus frameworks. • Review and disseminate the <i>Business Ethics for APEC SMEs</i> Resource Guide on Government Strategies to Encourage Ethical Business Conduct and voluntarily pilot one or more strategies within each APEC economy by 2025. Engage with the APEC Anti-Corruption and Transparency Experts Working Group (ACTWG).
<p><i>For Governments:</i> Realize the goals in the Tokyo Action Agenda to Promote Ethical Third Party Intermediary Relationships in the Medical Device Sector.</p>	<ul style="list-style-type: none"> • By 2021, indicate to the Initiative which enablers for Third Party SMIs (among other stakeholders) to advance the Guidance and the APEC Kuala Lumpur Principles have been implemented using the approaches contained within the Resource Guide on Government Strategies to Encourage Ethical Business Conduct.

⁹ The term “Healthcare Professionals” or “HCPs” includes those individuals and entities that purchase, lease, recommend, use or arrange for the purchase or lease of, or prescribe medical products. This includes both clinical and non-clinical individuals who make product-related decisions of the type described above. This is a broad definition, intended to encompass anyone with material influence over purchasing and/or prescribing decisions. Note that there may be laws and other codes applicable to relationships with Healthcare Professionals, including relationships with government employees.

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