

Tokyo, Japan, 20 July 2018

2018 APEC Business Ethics for SMEs Forum:

Tokyo Statement – Implementing Guidance for Ethical Third Party Intermediary Relationships in the Medical Device Sector

1. We, representatives from medical device, researchers, manufacturers, and third party intermediaries (such as distributors, wholesalers, and sales agents), healthcare providers and professional organizations, government agencies, and health regulatory authorities from across the APEC region, convened in Tokyo, Japan today to affirm the goals and actions that will realize implementation of APEC Guidance for Ethical Third Party Intermediary Relationships in the Medical Device Sector¹ (“the Guidance”) as encouraged by APEC SME Ministers in Ho Chi Minh City, Viet Nam on 15 September 2017. We do so with the knowledge that these efforts advance ethical business practices for SMEs as called for by the APEC Kuala Lumpur Principles², the APEC Nanjing Declaration³, and the *Business Ethics for APEC SMEs Initiative*.

2. We recognize that it is often necessary for medical device researchers and manufacturers (“Companies”) to contract with third party sales and marketing intermediaries (“Third Party SMIs”) to support their activities, enabling ongoing access for patients and health care professionals (“HCPs”) to innovative, reliable, and effective medical devices. Third Party SMIs serve an integral role in the medical device sector and a majority of them across APEC economies are small and medium-sized enterprises that contribute to employment and commercial activity in the APEC region.

3. We affirm that it is the responsibility of both Companies and Third Party SMIs, in active collaboration with relevant health system stakeholders, to implement high-standard ethical business practices into their daily activities. Taking into account a variety of risk-based factors, as well as international and local laws, Companies and Third Party SMIs should develop and adhere to codes of ethics and compliance programs that embrace the APEC Kuala Lumpur Principles and contain the seven provisions contained in the Guidance, including: written anti-bribery policy/procedure; risk assessment; diligence program; written contract; training and education; monitor/audit; and, appropriate corrective action.

4. Under the leadership of the *Business Ethics for APEC SMEs Initiative*, 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:

Goals	Actions
<i>Companies / Third Party SMIs: <u>Establish an open source, virtual resource portal by 2019</u></i>	<ul style="list-style-type: none">• In close collaboration with APEC economies and stakeholders, the <i>Business Ethics for APEC SMEs Initiative</i> will establish an open source / virtual resource portal for Companies and Third Party SMIs by 2019 that offers a diverse series of knowledge and implementation tools for small and medium-sized enterprises seeking to align with the Guidance.

¹ 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

² APEC Kuala Lumpur Principles for Voluntary Code of Ethics in the Medical Device Sector:

http://mddb.apec.org/Documents/2011/MM/SMEMM/11_smemm_009.pdf

³ APEC Nanjing Declaration on Promoting Ethical Environments in the Medical Device and Biopharmaceutical Sectors Through 2020:

http://mddb.apec.org/Documents/2014/MM/SMEMM/14_smemm_020a.pdf

**PRE-DRAFT FOR DELEGATES OF THE 2018 APEC BUSINESS ETHICS FOR SMEs FORUM
POSTED FOR ADVANCE REVIEW – 12 JULY 2018**

<p>Companies / Third Party SMIs: <u>Establish a voluntary certification mechanism on the Guidance by 2021</u></p>	<ul style="list-style-type: none"> • At least two APEC economies will partner with the Business Ethics for APEC SMEs Initiative by 2020 to pilot a voluntary, organizational certification mechanism on the Guidance, utilizing the platform established through the virtual resource portal. • Incorporating results from pilots, the virtual resource portal should launch a voluntary certification mechanism on the Guidance for all APEC economies by 2021, with at least 100 Third Party SMIs to complete certification by year one and at least 500 Third Party SMIs to complete certification by year two. By year one, at least 25 Companies will publicly recognize certification to the Guidance as a component of their compliance programs. By year two, at least 100 Companies will publicly recognize certification to the Guidance as a component of their compliance programs. • By 2019, the Business Ethics for APEC SMEs Initiative should set a certification threshold to reflect a specified, minimum percentage of Companies and Third Party SMIs within APEC member economies to complete/maintain this certification.
<p>Industry Associations (Companies / Third Party SMIs): <u>Implement codes of ethics or issue recommendations consistent with the Guidance by 2020</u></p>	<ul style="list-style-type: none"> • By 2019, APEC medical device industry associations will provide indication to the <i>Business Ethics for APEC SMEs Initiative</i> on whether the association code of conduct has adopted provisions in alignment with the Guidance. • By 2019, APEC medical device industry associations will inform their member Companies and Third Party SMIs about the virtual resource portal established by the Business Ethics for APEC SMEs Initiative. • By 2020, APEC medical device industry associations will affirm they have implemented a code of ethics that contains the provisions of the Guidance or will affirm that the association has issued specific recommendations for members that align with the Guidance. • By 2020, APEC medical device industry associations within pilot APEC economies will inform their member Companies and Third Party SMIs about the voluntary certification mechanism. • By 2021, APEC medical device industry associations will affirm they offer at least one annual training program to local Companies and Third Party SMIs on the Guidance. The annual training program may leverage the open source / virtual resource portal established for Companies and Third Party SMIs on the Guidance. • By 2021, APEC medical device industry associations outside pilot APEC economies will inform their member Companies and Third Party SMIs about the voluntary certification mechanism.

**PRE-DRAFT FOR DELEGATES OF THE 2018 APEC BUSINESS ETHICS FOR SMEs FORUM
POSTED FOR ADVANCE REVIEW – 12 JULY 2018**

<p>Governments: <u>Provide support in the utilization of a virtual, open source and voluntary certification mechanism</u></p>	<ul style="list-style-type: none"> By 2021, APEC government authorities represented on the APEC SMEWG should undertake at least one local program to facilitate awareness and utilization of the certification mechanism. This can include convening an in-person or virtual seminar for SMEs on the certification, linking the certification mechanism to a website that is frequented by SMEs in the local medical device sector, or issuing a media statement on the certification, among other similar opportunities.
<p>Healthcare Professionals: <u>Implement codes of ethics consistent with the Guidance</u></p>	<ul style="list-style-type: none"> By 2021, HCP organizations across APEC member economies should confirm they have implemented codes of ethics (codes of ethical conduct), related policies/practices, and communications activities that are consistent with the Guidance for the benefit of their members.
<p>All Stakeholders: <u>Implement joint policies and capacity building activities consistent with the Guidance</u></p>	<ul style="list-style-type: none"> By 2022, APEC economies and leading stakeholders will examine and pilot joint policies and capacity building activities that support implementation of the Guidance, including mechanisms that may encourage voluntary certification and the undertaking of routine training.

DELEGATES NOTE – This Statement’s Goals / Actions should align with the following “Implementation” provisions of the APEC Guidance welcomed by APEC SME Ministers in 2017:

Implementation

Cooperation among multiple stakeholders is necessary to promote an ethical business environment consistent with this guidance. Therefore, medical device sector industry associations, Companies, Third Party SMIs, HCPs, government authorities, and other stakeholders should consider:

- ***Implementing codes of ethics consistent with the principles set out above and additional steps to encourage the adoption of this guidance among their respective members and/or employees;***
- ***Encouraging the development and implementation of high-standard, aligned policies and practices consistent with this guidance;***
- ***Undertaking joint communication and training on this guidance and other relevant policies;***
- ***Encouraging medical device sector regulators and enforcement authorities to acknowledge and support this guidance set out above, and to support steps by stakeholders to implement effective guidance for ethical Third Party SMI relationships; and***
- ***Encouraging APEC economies to advance ethical collaborations consistent with this guidance, through regular communication, joint policies, joint capacity building, and other forms of collaboration.***