



**Asia-Pacific  
Economic Cooperation**

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**2018/SMEWG47/016**

Agenda Item: 13.1

**2018 APEC Business Ethics for SMEs Forum -  
Tokyo Declaration: Promoting Ethical Third Party  
Intermediary Relationships in the Medical Device  
Sector Through 2021 (Endorsed)**

Purpose: Information  
Submitted by: United States



**47<sup>th</sup> Small and Medium Enterprises  
Working Group Meeting  
Port Moresby, Papua New Guinea  
12-13 September 2018**

Tokyo, Japan, 20 July 2018

## 2018 APEC Business Ethics for SMEs Forum

### Tokyo Action Plan: Recommendations to Promote Ethical Third Party Intermediary Relationships in the Medical Device Sector through 2021

1. We, representatives from medical device researchers and manufacturers, third party intermediaries (such as distributors, wholesalers, and sales agents), industry and third party intermediaries' associations, healthcare providers and professional organizations, government agencies, health regulatory authorities and patient groups from across the APEC region, convened in Tokyo, Japan from 18-20 July 2018 for the APEC Business Ethics for SMEs Forum.

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

3. We reaffirm the APEC Guidance for Ethical Third Party Intermediary Relationships in the Medical Device Sector<sup>1</sup> ("the Guidance"), recognized by APEC SME Ministers in Ho Chi Minh City, Viet Nam on 15 September 2017. The Guidance advances ethical business practices for SMEs as called for by the APEC Kuala Lumpur Principles<sup>2</sup> (the "KL Principles"), the APEC Nanjing Declaration<sup>3</sup>, and the *Business Ethics for APEC SMEs Initiative* ("the Initiative"). The Guidance states that Companies and Third Party SMIs should develop and adhere to codes and compliance programs that embrace the KL 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.

4. Recognizing our shared commitment to ethical interactions that are in the best interest of patients and to the ability of the region's Third Party SMIs to be able to sustainably grow and trade, we agree on a collective vision to promote ethical third party intermediary relationships in the medical device sector.

5. We declare our intention to APEC SME Ministers, APEC Ministers, and APEC Leaders to work towards achieving the following goals. We call upon APEC economies and stakeholders to consider undertaking the following recommendations, respecting the diversity of healthcare systems:

Stakeholder and Goal	Recommendations
<b>Industry Associations (Company and/or Third Party SMI members):</b> <u>Double the number of associations that have implemented codes or issued recommendations consistent with the Guidance by 2021</u>	<u>Double the number of associations that have implemented codes of ethics or issued recommendations consistent with the Guidance by 2021</u> <ul style="list-style-type: none"><li>By 2019, APEC medical device industry associations should indicate to the Initiative whether the organization's code of ethics has adopted provisions in alignment with the Guidance (or has issued recommendations consistent with the Guidance).</li></ul>

<sup>1</sup> 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](http://mddb.apec.org/Documents/2017/MM/SMEMM/17_smemm_016.pdf)

<sup>2</sup> 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](http://mddb.apec.org/Documents/2011/MM/SMEMM/11_smemm_009.pdf)

<sup>3</sup> 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](http://mddb.apec.org/Documents/2014/MM/SMEMM/14_smemm_020a.pdf)

Stakeholder and Goal	Recommendations
<p><u>Double the number of associations with annual Third Party SMI training by 2021</u></p> <p><u>Develop at least one voluntary Third Party SMI certification model by 2021</u></p>	<ul style="list-style-type: none"> <li>By 2021, the number of APEC medical device industry associations that have implemented a code of ethics that contains the provisions of the Guidance (or have issued recommendations consistent with the Guidance) should double.</li> </ul> <p><u>Double the number of associations with annual Third Party SMI training by 2021</u></p> <ul style="list-style-type: none"> <li>By 2019, APEC medical device industry associations should indicate to the Initiative whether the organization holds at least one annual Third Party SMI training activity.</li> <li>By 2021, the number of APEC medical device industry associations that hold at least one annual Third Party SMI training activity should double.</li> </ul> <p><u>Develop a voluntary Third Party SMI certification model by 2021</u></p> <ul style="list-style-type: none"> <li>By 2019, at least one APEC medical device industry association should design a voluntary Third Party SMI certification mechanism.</li> <li>By 2020, the association(s) should pilot the Third Party SMI certification mechanism in at least two economies, each reaching over 1,000 distributors.</li> <li>By 2021, the association(s) should assess the results of the pilot program, incorporate key learnings, and share a certification model with all APEC member economies.</li> </ul>
<p><b>Governments:</b> <u>Develop measures that promote or incentivize Third Party SMIs to adhere to and advance the Guidance and the APEC Kuala Lumpur Principles</u></p>	<ul style="list-style-type: none"> <li>By 2019, the Initiative should identify existing government measures that promote or incentivize Third Party SMIs to adhere to and advance the Guidance and the APEC Kuala Lumpur Principles. Governments should present these measures at the 2019 APEC Business Ethics for SMEs Forum.</li> <li>By 2021, governments should indicate to the Initiative which measures have been developed and/or implemented since 2019.</li> </ul>
<p><b>HCPs &amp; HCP Organizations:</b> <u>Enhance awareness of and/or promote code of conduct alignment with the APEC Kuala Lumpur Principles</u></p>	<ul style="list-style-type: none"> <li>By 2019, the Initiative should develop resources to enhance HCP awareness of the APEC Kuala Lumpur Principles and the role of Third Party SMIs.</li> <li>By 2020, HCP organizations should consider aligning codes of conduct, related policies and practices, and communications activities with the APEC Kuala Lumpur Principles.</li> <li>By 2021, HCPs organizations should develop success metrics that advise the Initiative on improvements in HCP awareness of and/or code alignment with the APEC Kuala Lumpur Principles.</li> </ul>
<p><b>Business Ethics for APEC SMEs Initiative:</b> <u>Establish a virtual resource portal by 2019</u></p>	<ul style="list-style-type: none"> <li>By 2019, the Initiative should establish a virtual resource portal on <a href="http://klprinciples.apec.org">klprinciples.apec.org</a> that promotes ethical third party intermediary relationships in the medical device sector.</li> </ul>