



**Asia-Pacific
Economic Cooperation**

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Agenda Item: 16.1

Nanjing Declaration to Promote Ethical Environment in the Medical Device and Biopharmaceutical Sectors Through 2020

Purpose: Consideration
Submitted by: United States



**39th Small and Medium Enterprises
Working Group Meeting
Nanjing, China
3-4 September 2014**

Nanjing, China, 2 September 2014

2014 APEC Business Ethics for SMEs Forum:

Nanjing Declaration – *Promoting Ethical Environments in the Medical Device and Biopharmaceutical Sectors through 2020*

1. We, representatives from healthcare providers and professional organizations, anti-corruption agencies, health ministries, health regulatory agencies, economic ministries, medical device and biopharmaceutical associations, industry and patient organizations from across the APEC region, convened in Nanjing, China today to chart the future course of our joint efforts to advance the “Business Ethics for APEC SMEs Initiative” in the medical device and biopharmaceutical sectors. We do so with knowledge that nearly 1,000 stakeholder representatives have engaged in this initiative from all 21 APEC member economies to strengthen ethical business practices for the medical device and biopharmaceutical sectors, including more than 10,000 SMEs, and that this initiative has proven to be an effective model.

2. We reaffirm our support for The Kuala Lumpur Principles for Voluntary Codes of Ethics in the Medical Device Sector and The Mexico City Principles for Voluntary Codes of Ethics in the Biopharmaceutical Sector. These principles represent the highest global standards in ethical practices for each sector and strengthen the ability of SMEs to sustainably operate and engage in cross-border trade.

3. 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 endorsement of this initiative. We recall their statements guiding APEC economies to support the local elaboration and implementation of codes of ethics aligned with APEC principles for industry, healthcare professional organizations, and other stakeholders.

4. We extend our appreciation to the APEC SME Working Group for its leadership in convening industry, government and non-governmental organizations to develop the APEC principles, providing capacity building assistance to facilitate their implementation, and supporting the first APEC Business Ethics for SMEs Forum.

5. One year ago in Nusa Dua, Indonesia, we recognized that ethical collaboration among industry, healthcare providers and governments promotes broad patient access to life-saving and health-enhancing medical technologies and therapies and is essential to the development of new innovations that meet patient needs. We also agreed that each stakeholder has a responsibility to take further steps to promote an ethical environment. The Nusa Dua Statement¹ issued on 3 September 2013 established that each stakeholder has a unique and important role to promote ethical healthcare environments, including:

- ***The Medical Device and Biopharmaceutical Industry*** should adhere to high ethical standards, such as the APEC principles, as well as all applicable laws and regulations, as part of their mission to help patients by developing and making life-saving and health-enhancing medical technologies and therapies available.
- ***Healthcare Professionals*** have a duty to act in the best interests of patients and recognize the importance of their role in communicating the importance of interactions based on ethical principles, such as the APEC principles, including through complementary activities and ongoing dialogue with all stakeholders.
- ***Health Ministries and Health Regulatory Agencies*** should recognize the value of industry codes of ethics and encourage all stakeholders to support ethical principles, such as the APEC principles, and national and local industry codes of ethics.

¹ Nusa Dua (Bali) Statement: http://mddb.apec.org/Documents/2013/SMEWG/HLM/13_smewg37_hlm_statement.doc

- **Government and Private Procurement Entities** should procure health products and services based on transparent, ethical, clear, and accountable policies, processes and procedures.
- **Anti-corruption Authorities** should objectively apply clear laws, welcome industry self-regulation as complementary to law enforcement, and encourage all companies to adopt and adhere to uniform ethical principles, such as the APEC principles, and national and local industry codes of ethics.

6. Ethical interactions between industry and healthcare professionals are essential to provide healthcare providers and their patients with the information they need to make informed healthcare decisions. Recognizing our shared commitment to acting in the best interest 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 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:

Goals	Actions
<p><i>For the Medical Device and Biopharmaceutical Industry:</i> <u><i>Double the number of medical device and biopharmaceutical industry associations that have adopted codes of ethics from 33 in 2012 to 66 or more by 2015 and work toward universal adoption and implementation of the APEC Principles by 2020.</i></u></p>	<ul style="list-style-type: none"> • Convene the APEC Business Ethics for SMEs Forum on an annual basis (2015-2020) prior to the APEC SME Ministerial Meeting and hosted by the APEC chair economy. • Establish a task force with other stakeholders to secure funding for an “APEC Business Ethics Capacity Building Fund” by 2015 to support the Forum and associated capacity building for industry -- as well as governments, healthcare professionals and other stakeholders -- through 2020. • Formalize the “APEC Medical Device Working Group on Ethics” and “APEC Biopharmaceutical Working Group on Ethics” in 2014 with a mandate to: identify priority training areas for industry, governments, healthcare professionals and other stakeholders; implement training, including capacity building for industry associations with and without codes; formalize/manage each sector’s trainer network and online resources; and monitor progress, submitting an annual report to the “Business Ethics for APEC SMEs Initiative” for transmission to the APEC SME Working Group and other relevant APEC fora. • By 2015, the “APEC Medical Device Working Group on Ethics” and “APEC Biopharmaceutical Working Group on Ethics” will review the APEC principles to ensure that they continue to reflect the highest standards in business practices. • Establish an “APEC Code of Ethics Compendium for the Medical Device and Biopharmaceutical Sectors” by 2015 and updated annually thereafter to assist SMEs seeking to conduct business throughout the region. The compendium will contain a copy of each industry association’s most recent code of ethics and analysis undertaken by each sector’s working group indicating where there is alignment with the APEC principles. The compendium will be presented each year to the APEC SME Working Group, transmitted directly to governments, and made

	public for SMEs to access via the Business Ethics for APEC SMEs website (http://businessethics.apec.org).
<i>For the Medical Device and Biopharmaceutical Industry: <u>Implementation of association codes by a majority of member companies by 2017.</u></i>	<ul style="list-style-type: none"> By 2015, the “APEC Medical Device Working Group on Ethics” and “APEC Biopharmaceutical Working Group on Ethics” will: (a) convene a best practices exchange with APEC economies and industry associations to support member company code implementation; (b) develop training materials to facilitate code implementation by member companies; (c) monitor progress; and (d) report on the status of member company implementation in 2016 and 2017.
<i>For Governments: <u>Support and endorse local partnerships in APEC economies between relevant government ministries/agencies and the medical device and biopharmaceutical industries to advance industry’s voluntary efforts to strengthen ethical business practices.</u></i>	<ul style="list-style-type: none"> Support local partnerships in APEC economies between relevant ministries/agencies (e.g., health ministries and health regulatory authorities, government procurement entities, economic ministers and anti-corruption authorities) and the medical device and biopharmaceutical industries to advance industry’s voluntary efforts to strengthen ethical business practices (examples of partnership between government and industry include associations forming integrity pacts with relevant government ministries/agencies, the formation of a local business ethics centre, or governments actively supporting companies to develop and implement high-standard codes of ethics). Leverage the “APEC Medical Device Working Group on Ethics” and “APEC Biopharmaceutical Working Group on Ethics” to recommend and implement the capacity building required to support local partnerships. Use the “APEC Business Ethics Capacity Building Fund” to help fund capacity building activities.
<i>For Governments: <u>Support and endorse local partnerships in APEC economies between relevant government ministries/agencies and healthcare professional organizations.</u></i>	<ul style="list-style-type: none"> Support local partnerships in APEC economies between relevant ministries/agencies (e.g., health ministries and health regulatory authorities, government procurement entities, economic ministers and anti-corruption authorities) and healthcare professional organizations. Leverage the “APEC Medical Device Working Group on Ethics” and “APEC Biopharmaceutical Working Group on Ethics” to recommend and implement the capacity building required to support local partnerships. Use the “APEC Business Ethics Capacity Building Fund” to help fund capacity building activities.
<i>For Healthcare Professionals (HCPs)²: <u>Support development and implementation of HCP</u></i>	<ul style="list-style-type: none"> Develop an “APEC Consensus Framework for Ethical Collaboration” between the region’s medical device and biopharmaceutical industries and healthcare professional

² The term “Healthcare Professionals” 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 decisions. Note that there may be laws and other codes applicable to relationships with Healthcare Professionals, including relationships with government employees.

<p><u>codes of conduct consistent with the APEC Principles, working towards regional alignment by 2020.</u></p>	<p>organizations. Establish a work plan for joint collaboration to implement the Consensus Framework, including the development and implementation of HCP codes of conduct consistent with the APEC principles.</p> <ul style="list-style-type: none"> • Leverage the “APEC Medical Device Working Group on Ethics” and “APEC Biopharmaceutical Working Group on Ethics” to recommend and implement capacity building required to support implementation of the “APEC Consensus Framework for Ethical Collaboration”, including the development and implementation of HCP codes of conduct consistent with the APEC principles.
<p><i>For non-government organizations, in particular patient organizations:</i> <u>Promote ethical environments in the medical device and biopharmaceutical sectors.</u></p>	<ul style="list-style-type: none"> • Support partnerships with government agencies, HCPs and industry associations.