

# What you need to know about recent developments with the IFPMA, APEC, APACMed and other pharma/device codes

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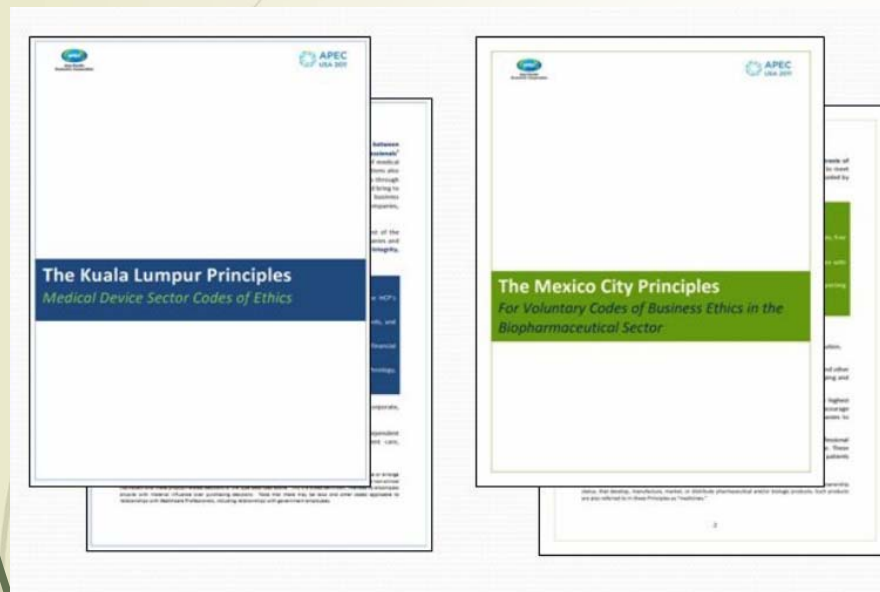
## 1. *Setting scene - in a nutshell all these codes have same aim*

- ▶ **IFPMA** - First enacted in 1981. Over arching voluntary code establishing promotion of ethical principles for the pharmaceutical industry globally. Current revision of the IFPMA Code of Practice came into effect on 1 September 2012. Further revisions expected.
- ▶ **APEC** - Asia-Pacific Economic Cooperation endorses and builds on IFPMA global code in all APEC member countries. Also endorses “ Mexico City Principles” for Voluntary Codes of Business Ethics in the Biopharmaceutical Sector and “ Kuala Lumpur Principles” for Voluntary Codes of Business Ethics in Medical Device/Tech Sector.
- ▶ **SMF**- Singapore Manufacturing Federation originally founded in 1932. More recently the Medical Technology Industry Group (MTIG) within SMF formed in 1998 and established its code to facilitate ethical interactions with healthcare professionals in Singapore.
- ▶ **APACMed** - Founded in 2014, Asia Pacific Medical Technology Association represents medical equipment, devices and in-vitro diagnostic companies in Asia Pacific. Code of Ethical Conduct for interactions with health care professionals revised in 2017.
- ▶ **SAPI** - Singapore Association of Pharmaceutical Industries has about 42 member companies 36 being international companies engaged in R&D/biopharmaceutical medicines. SAPI revised its Code of Conduct in 2018.

## APEC

- ▶ The *Business Ethics for APEC SMEs Initiative* is the world's largest public-private partnership to strengthen ethical business practices in target sectors.
- ▶ From 2012, the initiative more than doubled the number of medical technology and biopharmaceutical industry association codes of ethics – from 37 to 74 – across the APEC region, including within 10 economies where they previously did not exist.
- ▶ This work has expanded high-standards to over 18,000 member companies (of which over 13,000 are SMEs).
- ▶ This speed of this achievement is understood when recognizing that the region's first 37 codes in these sectors took over three decades to develop.
- ▶ Work is underway to begin scaling curriculum as well as to facilitate new model consensus frameworks that strengthen ethical practices across entire health systems, building on the first launch of such models in Canada and Peru in 2016.

## About the Business for APEC SMEs Initiative



Thanks to implementation efforts for the APEC Mexico City Principles that began in 2012,

**83 (out of 104) codes of ethics aligned with APEC principles, bringing 18,000+ companies (of which 13,000 are SMEs) under a code as part of the initiative' annual reports:**

Medical device: [Report on Code of Ethics Implementation](#)

Biopharmaceutical:

<http://mcprinciples.apec.org/CMFiles/2018Report.pdf>

# About the Business for APEC SMEs Initiative



- ▶ **Announcement of three consensus framework agreements (China, Japan, Australia)**
  - ▶ Examples include industry-hospital collaboration in areas such as education and training, research, advocacy, purchasing, resource allocation and policymaking. The aim is to uphold patient interests while opening up trade by freeing firms large and small of the high costs of corruption.
- ▶ **Successful launch and beta testing of virtual training programs**
  - ▶ “APEC Virtual Ethics for SMEs Compliance Program”
  - ▶ “APEC Distributor Compliance Portal”
- ▶ **Tokyo Declaration - an ambitious set of targets to increase third party adherence to high-standard business ethics practices.** Targets include that by 2021:
  - ▶ associations align their codes with the [APEC Guidance for Ethical Third Party Intermediary Relationships in the Medical Device Sector](#)
  - ▶ governments develop enablers for third parties to abide by principles consistent with the [APEC KL Principles](#)
  - ▶ HCPs expect third party behavior aligned with the APEC KL Principles; and
  - ▶ voluntary third party certification pilots to be completed.
- ▶ Full day workshops with Patient Organizations and Healthcare Professional organizations.

# IFPMA Code of Practice – Key changes for 2019

## The IFPMA

**Ethos puts trust  
at its center**



- ▶ **Gifts & other items to HCPs** (Section 7.5) Includes ban on gifts, added clarifications and alignment of IFPMA code to Member Association Codes.
- ▶ **Ban on Promotional Aids** ( Rx medicines) – non monetary reminders (*exclusion* OTC if relevant to HCP practice – Covered in Q&A).
- ▶ **Items of Medical Utility** – Modest, not expected, beneficial, occasional and can include company name.
- ▶ **Information/Educational Items that enhance patient care** note -new under Section 7.5, primarily for education purpose, not having independent value, may have company name, needs to be modest and consider cost as well as overall benefit to HCP in given year.

## *APACMed*

- ▶ The APACMed mission is to improve the standards of care for patients through innovative collaborations among stakeholders to jointly shape the future of healthcare in Asia Pacific.
- ▶ APACMed was established to provide a unifying voice for the medical devices, equipment and in-vitro diagnostics industry in Asia Pacific.
- ▶ APACMed is the first and only regional medical technology association that is headquartered in Asia, solely focused on matters of interest in Asia Pacific.
- ▶ Founded in 2014, and officially launched in April 2015, these last three years have been an extraordinary time for APACMed.
- ▶ The membership of APACMed comprises medical devices and diagnostic manufacturers, SMEs, and other industry associations.
- ▶ APACMed's Legal/Ethics & Compliance Committee formulated and issued to members Code of Ethical Conduct for Interactions with Health Care Professionals.

## *Elimination of Direct Sponsorship of HCPs to Third Party Educational Events*

Member support of Third Party Educational Events must at all times preserve the independence of medical and scientific education.

Effective 1 January 2018:

- ▶ Members no longer are permitted to directly pay the expenses of HCPs to attend or speak at Third Party Educational Events i.e. direct sponsorships.
- ▶ Members are no longer be permitted to select or influence the selection of HCPs to attend Third Party Educational Event, whether as delegates or faculty.

The change was been reflected in amendments to the APACMed Code.

This change is also consistent with laws, regulations, and codes of conduct of in-country industry associations in APAC and other regions around the world.



## Key Facts about SAPI

May 1966

**51** yrs

Members Companies

**36**

Associate Members

**6**

Affiliation

**IFPMA**

Code of Ethics & Compliance

**Self - regulation**

Medicines

**Research and Development  
based Companies**

## Changes to SAPI Code - Singapore

Most notable changes are amendments on '*Third Party Educational Events*' sponsorship under section 7.2.4.

Section	Description	w.e.f
7.2	Sponsorship	1 <sup>st</sup> Jan 2019
7.5.3	Items of Medical Utility	30 <sup>th</sup> Jan 2018

- (i) Member Companies must not directly and/or indirectly select or influence the **selection** of any HCPS to attend the event. All HCPs from both the public and private sectors should be independently selected by a decision making committee, professional body or medical association whereby selection criteria and processes are legitimate
- (j) No member Company or any representative/agent acting on its behalf may make registration, accommodation and /or travel **arrangements** for any attending individual HCP. **Payment** of any sponsorship must be paid only to the Organisers;



# Questions

**THANK YOU !**