The Mexico City Principles and What it Means to Pinoy MD's

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APEC, the Asia Pacific Economic Cooperation considers small and medium enterprises (SMEs) as the engine of economic growth and can serve as a key driver in global economic recovery as long as they are able to operate and innovate in open and transparent business environments.

Unethical behavior hurts economies: negative impact on inflation, decreased GDP, currency depreciation, reduced foreign investment and undermined health services.

Unethical behavior hurts individual business: increases the cost of doing business (through bribes & penalties), lowers sales growth and productivity, lowers the ability to enter new markets, constricts access to capital and undermines a company's financial growth in the long-term.

In October 2010, during the 17th APEC SME Ministerial Meeting in Gifu, Japan, the SME Ministers issued a joint Statement including a call for the development of APEC Codes of Ethics in sectors of export interest, beginning with the Medical Device Sector. A month later, in another Ministerial Meeting in Yokohama, they welcomed the development of other APEC Codes to improve and better align industry practices across the region and thus expanded their deliverables to include the following initiatives[1]:

1. **The Kuala Lumpur Principles for the Medical Device Sector**
2. **The Mexico City Principles for the Biopharmaceutical Sector**
3. **The Hanoi Principles for the Construction Sector**

In November 2011, the three Principles were endorsed by the APEC Ministers (Foreign & Trade Ministers) at the APEC Ministerial Meeting in Honolulu, Hawaii

The Mexico City Principles for Voluntary Codes of Business Ethics in the Biopharmaceutical Sector:

- recognizes that appropriate and ethical interactions help ensure that medical decisions are made in the best interests of patients
- assists the entire biopharmaceutical sector and ecosystem to align standards for ethical interactions (companies and industry associations, healthcare professional organizations and industry regulators and/or anti-corruption enforcement authorities)
- drafted by an Expert Working Group in Mexico City composed of 36 experts representing 14 APEC member economies the composition of which were representatives from small & large industries, government, academe and the civil society.

The MCP is governed by six underlying principles[2], namely:

a. **Healthcare and patient focus** - which means everything we do is intended to benefit patients;
b. **Integrity** - means dealing ethically, honestly and respectfully in everything we do;
c. **Independence** - means to respect the need of autonomous decision-making of all parties, free from improper influence;
d. **Legitimate intent** - means everything we do is for the right reasons, is lawful and aligns with the spirit and the values of these Principles;
e. **Transparency** – means a general willingness to be open about our actions while respecting legitimate commercial sensitivities and intellectual property rights; and
f. **Accountability** – means a willingness to be responsible for our actions and interactions.

While the Code is supposedly voluntary for companies, the Philippine Food and Drug Administration (FDA), in support of the Philippine commitment to APEC as a founding member, adopted the Principles for implementation through its Circular 024 s 2013.

The FDA released its Briefer on the MCP in June 2014 to clarify that the MCP is intended for the pharmaceutical companies with registered products in the Philippines. It clearly enumerates company activities that are allowed by the FDA in its marketing and promotion of products. Thus, it ensures that company interactions with the healthcare professionals are ethical and preserves the HCP's independence in arriving at medical decisions to protect patient safety.

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In the FDA Briefer, it emphasized how the MCP can affect a healthcare professional[3]:

1. The MCP protects the rights of the HCP to make decisions free from pharmaceutical influence as a result of gratis et. amore.
2. Second, HCPs are assured that drug product information is accurate, scientifically sound and any claims can be substantiated by clinical evidence. Information in promotional materials is not misleading and supports proper assessment of the risks and benefits of the products relative to its appropriate use.
3. Clinical trials are designed and conducted aligned to Good Clinical Practice with the intent to develop knowledge to benefit patients, advance science and medicine. The results published are factual and evidence based.
4. Any interaction with industry shall not be "colored" or tainted with possible misinterpretations from the public due to established close relationships, transparency is maintained at all times.
5. It guarantees that the HCP's role as a health provider has not been "commercialized" by industry and thus, undermines the HCP's position as an independent and trusted counselor to patients.
6. The HCP is assured that the company it deals with operates its business in a professional, ethical and transparent manner that ensures the appropriate use of medicines and supports the provisions of high quality healthcare. The said Code ensures that medicine promotion is carried out within a robust framework to support high quality patient care.
7. The HCP helps patients have access to affordable, quality medicines by doing away with expensive promotions which is a contributory factor in the high prices of medicines
8. And lastly, PMA's own Code of Ethics is upheld, revered and practiced by all its members.

In December 21, 2015, the Department of Health issued Administrative Order No. 2015 – 0053 entitled, "Implementing Guidelines on the Promotion and Marketing of Prescription Pharmaceutical Products and Medical Devices. Consistent with its policies to provide effective, safe and good quality drugs and medical devices, as well as to protect the people's rights to health, the AO is essential to maintain professionalism and high ethical standards in the interaction among the stakeholders in the pharmaceutical industry, including manufacturers, distributors, traders, healthcare professionals, healthcare-related institutions and patients' organizations. FDA further emphasized that the MCP is consistent with its current thrust to uphold the values of integrity, accountability, transparency and good governance.

The World Health Organization (WHO) described in 1993 "an inherent conflict of interest between the legitimate business goals of manufacturers and the social, medical and economic needs of providers and the public to select and use drugs in the most rational way." (WHO Europe, 1993).[4] However, the interaction between these stakeholders (scientists, physicians, pharmaceutical industry) will always exist due to the nature of the healthcare industry. Links between the health professions and the pharmaceutical industry have grown enormously in recent years and has become a source of conflicts-of-interest and unethical behavior. Such conflicts may be subtle and can easily be missed but in the end, lead to unethical demands from each stakeholder and ultimately affecting patient care. These conflicts occur in situations in which professional judgment regarding a primary interest such as research, education and patient care, may be unduly influenced by a secondary interest such as financial gain or personal prestige.[5] Though some HCPs would claim that such actions are usually done in good faith and with the best intentions, public perception may view it differently and cast doubt on the integrity of the medical profession. Thus, as physicians, we must always maintain our objectivity, and always act in the best interest of our patients.

References:

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3. **The Philippine Food and Drug Authority (FDA) Briefer on The Mexico City Principles: What It Means to Practicing Doctors**, 2014.
4. **World health Organization definition of Conflict of Interest**, 1993.
5. **T Lemmens and PA Singer.** Conflict of Interest in Research, Education and Patient Care. Canadian Medical Association Journal 1998; 159 (8): 960-965.