Republic of the Philippines
Department of Health
**OFFICE OF THE SECRETARY**

OCT 0 2 2014

**DEPARTMENT CIRCULAR**
No. 2014 - 0389

**SUBJECT: CREATION OF A COMMITTEE FOR THE ADOPTION OF MEXICO CITY AND KUALA LUMPUR PRINCIPLES**

**RATIONALE:**

Instances of unethical and inappropriate business practices in the pharmaceutical and medical device industries have been identified and recognized by the World Health Organization and the Asia-Pacific Economic Cooperation (APEC) member economies as inconsistent with the people's right to health and impediments to people's access to safe, effective and quality pharmaceutical and medical device products.

Unethical business practices have serious health and economic consequences such as elevated mortality rates, chronic illnesses, high cost of health care and increasing barriers to international market, as well as local trade.

There is a need to protect and promote safe, efficacious and cost effective biopharmaceutical products and medical services through adequate, consistent and objective information and appropriate regulation of the marketing and distribution of the said products.

APEC has endorsed certain principles to establish preventive measures and integrity systems to fight corruption and urge member countries to adopt and implement codes of business ethics for significant players in the medical device and biopharmaceutical sectors. These principles are embodied in two documents, namely: (1) The Mexico City Principles for Voluntary Codes of Business Ethics in the Biopharmaceutical Sector; and (2) the Kuala Lumpur Principles: Medical Device Sector Codes of Ethics.

President Benigno S. Aquino III signed these documents in November 2011, signifying the support and adherence of the Philippines, an APEC member, to these principles.

Further, the Philippines has committed to adhere to the APEC Principles (Healthcare and Patient Focus, Integrity, Independence, Legitimate Intent, Transparency, Accountability, Appropriateness and Advancement) to maintain professionalism and high ethical standards in the interactions among the stakeholders in the pharmaceutical industry, including manufacturers, distributors, traders, healthcare professionals, healthcare related institutions and patient organization.

The APEC codes cover the following pertaining to: Interactions with Healthcare Professionals, Promotional information and activities, Safety of medicines, Symposia and congresses, Informational presentations by company representatives, entertainment, educational items and gifts, support for continuing medical education, samples, consultant and speaker arrangement, compliance procedures and responsibilities, public sector relationship and procurement, clinical trials, company donations for charitable purposes, patient organizations and adherence to principles;

In the implementation of these APEC Principles, there is a need to create a Committee to develop guidelines to address the problems on unethical practices in the biopharmaceutical and medical device sectors.

In this regard, this Circular is issued for the creation of a Committee for the implementation of the APEC Ethical Principles.

**I. Creation of a Committee for the Implementation of APEC Ethical Principles.** A Committee for the Implementation of APEC Ethical Principles is hereby created composed of members from both public and private sectors.

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| **Chairman** | : | Undersecretary, Department of Health (designated by the Secretary of Health) |
| **Vice-Chairman** | : | Food and Drugs Administration Director General |

**Members**:

1. Director, National Center for Pharmaceutical Access and Management
2. Director, National Center for Health Promotion
3. Representative, Professional Regulatory Commission
4. Representative, Professional Regulatory Board of Medicine
5. President, Pharmaceutical Healthcare Association of the Philippines
6. President, Philippine Chamber of Pharmaceutical Industries
7. President, Philippine Medical Association
8. President, Philippine Hospital Association
9. President, Philippine Hospital Association of the Philippines
10. President, Philippine Association of Medical Device Regulatory Affairs Professionals
11. Presidents of eight (8) Specialty Societies:
    - Philippine College of Physicians
    - Philippine College of Surgeons
    - Philippine Pediatrics Society

- Philippine Obstetrical and Gynecological Society
- Philippine Academy of Family Physicians
- Philippine Society of Anesthesiologists
- Philippine College of Radiology
- Philippine Society of Pathologists

The Chairman of the Committee shall issue the necessary invitation to the Professional Regulatory Commission and to the private sectors requesting their representative to the Committee.

The members from the government sector shall have rank not lower than a Director. The members from the private sector may be represented by their duly authorized Vice-President/Deputy.

**II. Functions**. The Committee shall have the following functions:

a. Formulate and develop the Guidelines for the adoption of the two (2) APEC ethical principles;
b. Oversee and monitor the implementation of the Guidelines;
c. Collaborate and coordinate with other non-member agencies both in public and government sectors as may be necessary;
d. Create Guidelines, rules and regulations including possible penalties and sanctions for violations in accordance with existing laws, as may be necessary, related, incidental, or consistent with the purpose, intent and objective of this Circular;
e. Submit to the Office of the Secretary the required reports documenting the status of the guideline implementation; and
f. Perform other functions as may deem necessary to carry out the provisions of this Circular, or as the Secretary may direct.

**III. Parameters in theFormulation of Implementing Guidelines**. The development of comprehensive and sustainable implementing guidelines shall include, but not limited to the following:

a. Creation of policies and programs to address the varied aspects of ethical pharmaceutical business practice including advocacy, management and regulation;
b. Strengthening the surveillance, monitoring and evaluation capacity of the implementing agencies in terms of pharmaceutical promotion of the involved stakeholders;
c. Ensuring the adherence/compliance of companies and industry association to the ethical standards/principles as stipulated in the Mexico City and Kuala Lumpur declarations;
d. Institutionalization of ethical practice in the healthcare system through continuous, training and education; and
e. Conduct of research and local studies on the impact of standardization of the code of ethics among various stakeholders.

**IV. Power of the Committee to Call upon any officer or employee of the Department Health**. In the performance of its functions, the Committee may call upon any officer or employee of the Department of Health or its attached agencies, and request assistance of all other officers and employees of other government agencies and the private sector as the circumstances and exigencies require.

**V. Timelines**. The Committee shall submit the draft Guidelines to the Secretary of Health for approval within ninety (90) days from effectivity of this Circular. Thereafter, the Committee shall oversee the implementation of said Guidelines.

**VI. Funding**. The funds necessary for the implementation of this Circular shall be taken from the available funds of the Department of Health and the Food and Drugs Administration, subject to budgetary, accounting and auditing rules and regulations.

**VII. Repealing Clause**. All orders, circulars, rules, regulations, issuances or parts thereof, which are inconsistent with any of the provisions of this Circular are hereby repealed or modified accordingly.

**VIII. Effectivity**. This Circular shall take effect immediately.

**ENRIQUE T. ONA**, MD, FPCS, FACS
Secretary of Health