



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



05 September 2013

FDA Circular
No. **2013-024**

SUBJECT: Adoption and Implementation of “The Mexico City Principles for Voluntary Codes of Business Ethics in the Biopharmaceutical Sector”

I. BACKGROUND

During the 17th APEC Small and Medium Enterprises (SME) Ministerial Meeting, the Ministers issued a Joint Ministerial Statement to promote SME cooperation for innovative growth in the APEC Region. Among others, the Ministers agree that corruption imposes a significant market access barrier and high costs for SMEs. To address this challenge, they endorsed principles for voluntary codes of business ethics for the medical device, biopharmaceutical, and construction/engineering sectors. They recognize the importance of working to raise awareness of these principles. They welcome progress in implementing these principles, through the development of codes of ethics by industry associations and companies and capacity building efforts. They called on other relevant stakeholders, such as professional organizations, to implement voluntary codes consistent with these principles. They urged industry regulators, anti-corruption enforcement authorities, and the relevant entities to encourage, advance, and facilitate acceptance of voluntary industry codes and ethical collaborations consistent with these codes.

The Joint Ministerial Statement paved the way for the “Business Ethics for APEC SMEs” project.

After several meetings of the Expert Working Group, the Ministers endorsed the adoption and implementation of the Kuala Lumpur (KL) Principles for Medical Devices Sector Codes of Ethics during the next APEC SME Meeting. The KL Principles served as the first example of adherence to the APEC Principles for Voluntary Codes of Business Ethics.

The Ministers called for the development of additional sets of voluntary ethical principles or codes of ethics in sectors, including the biopharmaceutical sector, where SMEs are important stakeholders. With the tireless efforts of the Expert Working Group, “The Mexico City Principles for Voluntary Codes of Business Ethics in the Biopharmaceutical Sector”, often referred to as the “Mexico City Principles”, was officially endorsed by the APEC Ministers for adoption by all industry sectors of the member countries on a voluntary basis.

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II. RATIONALE

In delivering the best quality healthcare to patients, it is essential that professionalism and high ethical standard are maintained between the biopharmaceutical companies, the health professionals, and the regulatory body. For the biopharmaceutical companies and the health professionals, ethical business practice must exist to achieve their social and economic objectives.

Lack of consistent ethical standards increases the costs of doing business, which in turn lower sales growth, productivity and the ability to enter new markets, constriction in the access to capital, and may go as far as corruption, bribery, and additional sanctions and penalties from regulatory bodies.

To avoid these unnecessary impediments to the growth of the Biopharmaceutical Sector, The Mexico City Principles was created with the aim to:

- significantly reduce ethics compliance costs for SMEs by providing greater clarity and a collective understanding of what constitutes appropriate interactions with healthcare professionals to increase the benefit patients receive and enhance the ethical practice of medicine;
- facilitate the safe and appropriate conduct of clinical research and assure that patients can benefit from objective and balanced research;
- provide a more cost-effective way to access new APEC markets through lower risk of enforcement action and lower compliance cost;
- position SMEs for greater contracting opportunities with large multi-national corporations in the global supply chain by raising awareness of the new ethics obligations required by large companies; and
- Help ensure that medical decisions are made in the best interest of patients by advancing appropriate interactions between health care professionals and companies.

III. SCOPE

This Order shall apply to all drug establishments regulated by the FDA, the FDA as an organization and its officials and healthcare professionals, as well as other stakeholders like media and advertisement firms.



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IV. OBJECTIVE

The objectives of this Circular are as follows:

1. To officially adopt and implement “The Mexico City Principles for Voluntary Codes of Business Ethics in the Biopharmaceutical Sector”, attached as Annex A; and
2. To provide guidelines on the implementation of the Mexico City Principles.

V. GUIDELINES

1. “The Mexico City Principles for Voluntary Codes of Business Ethics in the Biopharmaceutical Sector” (Annex 1) shall be implemented pursuant to the provision of R.A. No. 9711, also known as the “FDA Act of 2009”, in Section 4.o., which mandates FDA to prescribe standards, guidelines, and regulations with respect to information, advertisements and other marketing instruments and promotion, sponsorship, and other marketing activities.
2. The guidelines for applications and approval of promotional, advertisement, and/or sponsorship materials for pharmaceutical and biological products, among other health products, shall be formulated and issued by the Center for Drug Regulation and Research (CDRR).
3. The CDRR shall implement compliance with the Mexico City Principles and, among others, monitor advertisements and other marketing instruments and promotion, sponsorship, and other marketing activities in the country.
4. All monitoring, surveillance, and investigations on complaints and violations pertinent to the provisions of Section 4.o., of the FDA Act of 2009, and other pertinent rules and regulations, shall be conducted with the assistance of the Regional Field Operation (RFO) Unit.
5. All sanctions and penalties in violation of this Circular shall be imposed by the CDRR in consultation with the Office of the FDA Director General.
6. The CDRR shall issue guidelines, rules and regulations that are consistent with this Circular and the Mexico City Principles in consultation with the FDA Director General.



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VI. SANCTIONS

Any violation of this FDA Circular shall be a ground for filing appropriate administrative charges and/or imposition of administrative sanctions such as, but not limited to, imposition of fines, suspension, cancellation or revocation of any license, permit or registration issued by FDA.

VII. REPEALING CLAUSE AND SEPARABILITY CLAUSE

All other issuances concerning ethical practices in the pharmaceutical industry with respect to information, advertisements and other marketing instruments and promotion, sponsorship, and other marketing activities, among others, that are inconsistent with this Circular are hereby repealed, revised and modified accordingly. In case any part, term or provision of this Circular is declared contrary to law or unconstitutional, other provisions which are not affected shall remain in force and in effect.

VIII. EFFECTIVITY

This Circular shall take effect immediately.


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