The Code of Ethics of the Laboratory Medicine Specialists

Laboratory medicine (LM) specialists shall conduct in a manner that does not bring into disrepute the discipline and the profession of Laboratory Medicine. They shall value integrity, impartiality and respect for persons and evidence and shall seek to establish the highest standards of quality and ethics in their work as LM specialists.


LM specialists in their professional work, while cooperating and communicating with patients, between each other or with other professional specialists shall abide to values and principles of this Code of Ethics:

1. **Quality and excellence.** LM specialists shall put their knowledge and ability concerning laboratory diagnostics (including the indication for analyses, the reliability of the results, the interpretation of results and scientific research) at the service of diagnosis, therapy and prevention of human diseases. At all times, they shall act in the best interests of patients, subject to any over-riding legal requirements, with the highest standards of competency and integrity.

2. **Continuous professional development.** To optimally fulfil their duties and in accordance with what is regarded as good practice in their profession and having regard to the laws of the Republic of Lithuania, the LM specialists shall:
   - maintain and develop their competence at the highest level of quality by following all relevant (scientific and practical) developments concerning health care in general and Clinical Chemistry and Laboratory Medicine, by participating in relevant training courses and other appropriate continuous professional development programmes throughout their working life, and by practicing their profession on a regular basis;
• accept assignments only within their area of competence; beyond this limit, they will seek the collaboration of appropriate experts;
• keep up-to-date with statutory codes of practice which affect their work.
LM specialists will display their commitment to the profession of Laboratory Medicine by taking part in the activities of the Lithuanian Society of Laboratory Medicine, notably those which promote the profession, and contribute to continuing training of their members.

3. **Compliance with codes of ethics and conduct.** LM specialists shall comply not only with the provisions of this Code of Ethics but also codes of ethics of relevant healthcare fields until they do not compromise this Code of Ethics and legislative provisions of the Republic of Lithuania. LM specialists shall avoid any situation giving birth to the conflict of private and public interests, shall not engage in the activities which create circumstances for risk of corruption to appear. According to the laws of the Republic of Lithuania they shall provide the information on their activities to the public, state governmental and local self-governmental institutions.

4. **Honesty and integrity.** The professional integrity and intellectual honesty of the LM specialists shall be the guarantee of their impartiality of analysis, judgment and consequent decisions. The LM specialists shall always avoid deceit in professional and scientific respect, such as fraud, plagiarism, concealment, improper omission of information, and expressing incorrect or misleading opinions.

5. **Confidentiality.** LM specialists will ensure that information about a patient or other individual is not disclosed to others except in the Republic of Lithuania laws specified circumstances.

6. **Relationship with other specialists.** LM specialists shall always act with courtesy, honesty and integrity in their relationships with other healthcare professional specialists, shall respect their dignity, opinion, beliefs and values, shall appreciate work done by other health professionals including colleagues.

7. **Conflict with moral and ethical beliefs.** LM specialists are not obliged to offer to provide a professional service in ways which conflict with their own moral or religious beliefs, but must respect the moral, religious and cultural beliefs of individual patients. If LM specialists have agreed to provide a service, they must set aside any personal religious, cultural, philosophical or other convictions. They must ensure equitable access to their services to all who are entitled to use them, not discriminating individuals by gender, age, language, ethnicity, sexual orientation, marital status, education, disability, religion, beliefs or political views.

8. **Delegation and supervision.** As head and/or member of the team operating in the medical laboratory, the LM specialist will, given the specific circumstances of the situation concerned:
• obtain a clear definition of the services required of him and/or his team;
• ensure that all activities in the laboratory are organized and executed as accurately and as quickly as possible;
• protect the safety and well-being of his colleagues and be conscious of nature and the environment;
• show respect for superiors, colleagues and subordinates by taking due account of their requirements and aspirations, provided they conform to the laws and ethics of their profession;
• strive for a high level of technical achievement which will also contribute to and promote a healthy and agreeable environment for his colleagues;
• ensure that any member of support staff to whom a task is delegated has the knowledge, skills and competencies necessary to undertake that task effectively and efficiently, and that appropriate supervision is in place;
• retain responsibility for the task delegated, except when the delegated person is at the same level of professional qualification.

9. **Marketing (advertising, public relations) and provision of information.** LM specialists in both the public and private health sectors shall ensure that any publicly provided information on Laboratory Medicine services is accurate, honest, legal, decent and proportionate, and focused solely on the professional services offered. LM specialists shall not provide information which does not meet the reality and is misleading. They shall always ensure published advertisements or performed marketing actions are honest and objective, but not derogatory to other healthcare services providers.

Approved by the Board of the Lithuanian Society of Laboratory Medicine on 20\textsuperscript{th} November 2015 (protocol No. 4).
Communication/Collaboration

Policy #7-?:
Relationship with Industry

Scope:
Basis of AACC’s relationship with industry.

Purpose:
To define AACC’s relationship with industry.

Policy Statement:
1. The AACC is an international scientific/medical society of clinical laboratory professionals, physicians, research scientists and other individuals involved with clinical chemistry and related laboratory medicine disciplines. Its members hold positions in academia, hospitals, private laboratories, regulatory agencies as well as the in vitro diagnostic and pharmaceutical industries.

2. The AACC’s annual meeting, in addition to scientific education, provides its members and non-members with the world’s largest exposition dedicated to in vitro diagnostic testing and equipment, commercial laboratories, and original equipment manufacturers (hereafter referred to as industry).

3. AACC intends that its agenda and educational programs remain highly credible, of high quality, independent and free of commercial bias.

4. Industry makes important contributions to medical progress through development of new devices, and industry supports the profession by funding research, educational programs and awards that might not otherwise be possible. Therefore, it is AACC policy that:

   a. AACC, a member-oriented professional society, is financially autonomous of industry (i.e., is not an arm of industry). AACC does not need to be, nor should it strive to be, free of industry support. Therefore, AACC focuses on managing any potential conflicts of interest rather than eliminating monetary support from industry.

   b. Members who work in industry enjoy the full rights and privileges of AACC membership including serving in elected positions, serving on committees, and participating in AACC educational programs as planners and speakers. All AACC members are required to complete conflict of interest disclosure forms when serving the association in various leadership positions.

   c. AACC's educational programs are clearly distinguished from marketing, and educational programs are developed by AACC members and staff in accordance with AACC's Policy on Commercial Support for Educational Programs. Industry support of educational events is permitted if the funding entity is separated from the planning process and funding is not directed to support an individual speaker or presentation.
d. AACC requires all speakers to disclose potential conflicts of interest before and at the time of presentation.

e. Because laboratory measurements depend on specific equipment and reagents, some types of educational programs may include references to commercial products. In those situations, the educational programs must address scientific content and avoid promotional statements.

f. Industry may develop separate industry-sponsored symposia, workshops and conferences in conjunction with AACC meetings, but they must be clearly identified as such and a statement must be made at the beginning of each session that AACC does not endorse the content of industry programs.

g. The exhibit floor at any AACC meeting is clearly distinguished as a marketplace. Industry can purchase booth space at AACC meetings, but booths are not in the obligate path to scientific or educational sessions. Offering of educational or de minimis gifts is permissible. The AACC will not place the names or logos of companies or products on AACC-distributed items (such as bags, notebooks, lanyards, pens etc.).

h. AACC may share mailing lists with industry as long as members have a choice of opting out of having their email address shared with third parties.

i. Paid advertising in AACC publications is acceptable as long as it is clearly identifiable as such.

j. AACC does not accept funding from industry to develop clinical practice guidelines (clinical practice guidelines are systematically developed statements designed to assist the provider and the patient in making decisions regarding ordering or interpreting laboratory tests for diagnosis, management and treatment for specific clinical circumstances).

k. The term clinical practice guidelines should not be construed as all guidelines. There are other guidelines developed by AACC relating to technology, measurement procedures, laboratory operation, and related topics. Each of these will be handled on a case-by-case basis regarding acceptance of financial support from industry.

l. AACC accepts funding from industry for such things as awards, research grants, travel grants and scholarships. The recipients of such funds are selected by AACC committees not the financial donors. Awards may not be named for industry supporters but the source of funding may be recognized.

m. AACC does not endorse commercial products.

Review and Revision:
September 10, 2011
AUSTRALASIAN ASSOCIATION OF CLINICAL BIOCHEMISTS
Affiliated with the INTERNATIONAL FEDERATION OF CLINICAL CHEMISTRY AND LABORATORY MEDICINE
ASIAN AND PACIFIC FEDERATION OF CLINICAL BIOCHEMISTRY

Code of Ethics

Preamble
The Code of Ethics of the Australasian Association of Clinical Biochemists (AACB) sets forth the principles and
standards by which clinical laboratory professionals practice their profession.

I. Duty to the Patient
Clinical laboratory professionals are accountable for the quality and integrity of the laboratory services they provide.
This obligation includes maintaining individual competence in judgement and performance and striving to safeguard
the patient from incompetent or illegal practice by others.

Clinical laboratory professionals maintain high standards of practice. They exercise sound judgment in establishing,
performing and evaluating laboratory testing.

Clinical laboratory professionals maintain strict confidentiality of patient information and test results. They safeguard
the dignity and privacy of patients and any samples removed from them. They provide accurate information to other
health care professionals about the services they provide.

II. Duty to Colleagues and the Profession
Clinical laboratory professionals uphold and maintain the dignity and respect of our profession and strive to maintain a
reputation of honesty, integrity and reliability. They contribute to the advancement of the profession by improving the
body of knowledge, adopting scientific advances that benefit the patient, maintaining high standards of practice and
education, and seeking fair socio-economic working conditions for members of the profession.

Clinical laboratory professionals actively strive to establish cooperative and respectful working relationships with other
health care professionals with the primary objective of ensuring a high standard of care for the patients they serve.

Clinical laboratory professionals demonstrate honesty and integrity in business dealings with manufacturers, suppliers,
competitors and customers.

III. Duty to Society
As practitioners of an autonomous profession, clinical laboratory professionals have the responsibility to contribute
from their sphere of professional competence to the general well being of the community.

Clinical laboratory professionals comply with relevant laws and regulations pertaining to the practice of clinical
laboratory science and actively seek, within the dictates of their consciences, to change those which do not meet the
high standards of care and practice to which the profession is committed.

Clinical laboratory professionals ensure the cost-effective application of health-care pathology funds, guarding against
waste, inefficiency and unnecessary duplication.

Pledge to the Profession
As a clinical laboratory professional, I strive to:
✓ Maintain and promote standards of excellence in performing and advancing the art and science of
  my profession.
✓ Facilitate the training and continuing education of new members of the profession.
✓ Preserve the dignity and privacy of others.
✓ Uphold and maintain the dignity and respect of our profession.
✓ Seek to establish cooperative and respectful working relationships with other health professionals.
✓ Contribute to the general well being of the community.

I will actively demonstrate my commitment to these responsibilities throughout my professional life.
THE CODE OF PROFESSIONAL CONDUCT
OF
THE ASSOCIATION FOR CLINICAL BIOCHEMISTRY AND LABORATORY MEDICINE

The Code of Conduct applies to all individual Members of the Association for Clinical Biochemistry and Laboratory Medicine, including Emeritus, Honorary, Fellow, Ordinary, Federation, Retired, Temporarily Retired and Student.

All Members having signed an application form agree to abide by the constitution and Bye-laws of the Association as currently in place and amended from time to time.

All Members agree that by being appropriately qualified and practising in the UK they are obliged to comply with the Code of Conduct established by their appropriate registration body; the Health and Care Professions Council (HCPC), the General Medical Council (GMC) or other body, where a registration body exists for that health professional.

Members agree to comply with the Code of Conduct of their employer.

Members agree that they have a duty to:

a. Exercise their professional skills and judgement to the best of their ability and discharge their professional responsibilities with the highest standards of competence and integrity

b. Conduct themselves honourably in the practice of their profession

c. Maintain good standards of laboratory and clinical practice

d. Keep their knowledge and skills up to date and shall keep evidence of their continuing professional development to such standards as are required for audit

e. Keep up to date with statutory Codes of Practice which affect their work

f. Keep as confidential any information obtained during the course of their professional practice

g. Respect patients’ trust and not abuse their professional position to establish improper relationships with patients, to put pressure on patients to give or lend money or other benefits, to directly or indirectly recommend treatments or investigations which are not in their interests, withhold appropriate investigations treatments or referrals or put pressure on patients to accept private investigations or treatment

h. Report concerns to employers or registration bodies where they believe that a doctor’s or other colleague’s health, conduct or performance is a threat to a patient

i. Treat colleagues fairly and not make any patient doubt a colleague’s ability, knowledge or skills by making unnecessary or inappropriate comments about them

j. Work constructively within a team, respecting colleagues and communicating and co-operating with other health professionals and all others caring for patients

k. Ensure that where work is delegated, colleagues are of suitable experience and competence to perform the tasks delegated to them and ensure that they are armed with sufficient information to provide a good standard of service

l. Further the interests and objectives of the Association for Clinical Biochemistry and Laboratory Medicine but agree not to give the impression that they are acting or speaking for the Association unless they are authorised to do so

m. Conduct all research with honesty and integrity, following all aspects of research protocol, only accepting payments approved by a research ethics committee, recording results truthfully and maintaining adequate records. Members agree to only make justified claims for authorship and to report evidence of fraud or misconduct in research to an appropriate person or authority.

Members agree that they will maintain professional standards at all times, keeping up to date with amendments to this Code of Conduct, the Association’s Bye-laws and the Guidance/Regulations of their registration body.

This Code is not exhaustive and Members acknowledge that they will always be prepared to explain and justify their actions and decisions to the Association or their registration body if so required.
Code of Professional Conduct

Medical laboratory professionals are dedicated to serving the healthcare needs of the public. The welfare of the patient and respect for the dignity of the individual shall be paramount at all times.

Code of Professional Conduct

- Medical laboratory professionals are dedicated to serving the healthcare needs of the public. The welfare of the patient and respect for the dignity of the individual shall be paramount at all times.
- Medical laboratory professionals work with other health care professionals, to provide effective patient care.
- Medical laboratory professionals shall promote the image and status of their profession by maintaining high standards in their professional practice and through active support of their professional bodies.
- Medical laboratory professionals shall protect the confidentiality of all patient information.
- Medical laboratory professionals shall take responsibility for their professional acts.
- Medical laboratory professionals shall practise within the scope of their professional competence.
- Medical laboratory professionals shall endeavour to maintain and improve their skills and knowledge and keep current with scientific advances. They will uphold academic integrity in all matters of professional certification and continuing education.
- Medical laboratory professionals shall share their knowledge with colleagues and promote learning.
- Medical laboratory professionals shall be aware of the laws and regulations governing medical laboratory technology and shall apply them in the practise of their profession.
- Medical laboratory professionals shall practise safe work procedures at all times to ensure the safety of patients and co-workers and the protection of the environment.
Code of Practice: Relationship between IFCC and its Corporate Members

Introduction:

This document sets out a Code of Practice for the working relationship between IFCC and its Corporate Members. The document has been approved by both the IFCC Executive Board and by the IFCC Corporate Members.

The Code of Practice has been developed from the AdvaMed Code of Ethics as applied by the American Association for Clinical Chemistry.

International Federation of Clinical Chemistry and Laboratory Medicine (IFCC):

1. The IFCC is an international scientific/medical society of clinical laboratory organizations that represent professionals, physicians, research scientists and other individuals involved with clinical chemistry and related laboratory medicine disciplines. Its volunteers hold positions in academia, hospitals, private laboratories, regulatory agencies as well as the in vitro diagnostic and pharmaceutical industries.

2. The IFCC’s meetings, in addition to scientific education, provide its members and non-members with an exhibition dedicated to in vitro diagnostic testing and equipment, commercial laboratories, and original equipment manufacturers (hereafter referred to as industry).

3. IFCC has a category of membership (Corporate Members) that is open to any company that has an interest in the practice of clinical laboratory science/medicine.

4. Industry makes important contributions to medical progress through development of new devices, and industry supports the profession by funding research, educational programs and awards that might not otherwise be possible.

5. The following Code of Practice has been developed so that the IFCC agenda and educational programs will remain highly credible, of high quality, independent and free of commercial bias.

Code of Practice:

1. IFCC is financially autonomous of industry (i.e., is not an arm of industry). However, IFCC does not need to be, nor should it strive to be, free of industry support. Therefore, IFCC focuses on managing any potential conflicts of interest rather than eliminating monetary support from industry.

2. Members who work in industry enjoy the full rights and privileges of IFCC membership including serving in elected positions, serving on committees, and participating as volunteers in IFCC’s educational programs as planners and speakers. All IFCC volunteers are required to complete conflict of interest disclosure forms when serving the association in various leadership positions.

3. IFCC’s educational programs are clearly distinguished from marketing, and educational programs are developed by IFCC volunteers and staff. Industry support of educational events is permitted if the funding entity is separated from the planning process and funding is not directed to support an individual speaker or presentation.

4. IFCC requires all speakers to disclose potential conflicts of interest before and at the time of presentation.

5. Because laboratory measurements depend on specific equipment and reagents, some types of educational programs may include references to commercial products. In those situations, the educational programs must address scientific content and avoid promotional statements.

6. Industry may develop separate industry-sponsored symposia, workshops and conferences in conjunction with IFCC meetings, but they must be clearly identified as such and a statement must be made indicating that IFCC does not endorse the content of industry programs.
7. The exhibit floor at any IFCC meeting is clearly distinguished as a marketplace. Industry can purchase booth space at IFCC meetings, but booths are not a requirement for scientific or educational sessions. Offering of educational or small gifts is permissible.

8. IFCC may share mailing lists with industry as long as members have a choice of opting out of having their email address shared with third parties.

9. Paid advertising in IFCC publications is acceptable as long as it is clearly identifiable as such.

10. IFCC does not normally accept funding from single companies to support specific scientific or clinical projects. IFCC will invite all of its Corporate Members (and occasionally other companies) to contribute shared funding to such specific projects. Examples of these projects include method standardization/harmonization and clinical practice guidelines.

11. IFCC may accept funding from single companies for educational projects as long as they are free from commercial bias and do not imply IFCC endorsement of any product. Each case will be handled on an individual basis.

12. IFCC may accept funding from industry for such things as awards, research grants, travel grants and scholarships. The recipients of such funds are selected by IFCC committees not the financial donors. Awards may not normally be named for industry supporters but the source of funding may be recognized.

13. IFCC does not endorse commercial products.

Approved by the IFCC Executive Board
April 2013

Approved by IFCC Corporate Members
April 2013
Ethics Guidelines

On three occasions dating back more than 20 years, AACC’s Board of Directors has endorsed 10 principles of ethical conduct covering standards of professional conduct and development, healthcare practice, and research for the laboratory medicine profession. These guiding statements reflect the Association’s commitment to improving health and healthcare.

Preamble:

Members of the American Association for Clinical Chemistry endorse the following principles of ethical conduct in their profession, including clinical procedures, research and development, teaching, management, administration, and other forms of professional service:

Principles of Ethical Conduct

I will:

1. Uphold standards of professionalism, be honest in all professional endeavors, and maintain a high level of personal integrity.
2. Avoid scientific and professional misconduct including, but not limited to fraud, fabrication, plagiarism, concealment, inappropriate omission of information, and making false or deceptive statements.
3. Report any health care professional who engages in fraud or deception or whose deficiency in character or competence jeopardizes patient care or other personnel.
4. Maintain a high level of quality in the product(s) of my professional endeavors, including validity and reliability of test results, interpretive opinions, publications, and scientific research.
5. Respect the privacy and confidentiality of protected health information encountered during the course of my professional activities in accordance with legal and ethical obligations.
6. Continuously strive to augment my professional qualifications, knowledge, and skills, and present them accurately.
7. Promote the safety and welfare of patients, employees, co-workers, colleagues, the public, and the environment.
8. Avoid, or promptly disclose and work to resolve, actual or potential conflicts of interest.
9. Encourage open and honest discussion among physicians, other healthcare providers and/or facility managers regarding disclosure to patients of information about medical errors, if such information is material to any patient’s well-being.
10. Comply with relevant laws and seek to change them when they are contrary to the best interests of the patient.

Adopted by the AACC Board of Directors
June 15-17, 1990
Reaffirmed with editorial changes July 19, 2003
Reaffirmed with editorial changes November 9, 2007
We, members of the Philippine Society of Pathologists and as physicians, imploring divine guidance for a desirable professional ethics, providing competent practice in laboratory medicine with compassion and respect for human dignity and activities imposed for law and tradition, voluntarily accept without mental reservation and purpose of evasion, tenets that best serve the interest of patient care, professional conduct and relation applicable to all.

With these affirmations, I do adhere and profess the following:

1. I Shall Not Solicit or knowingly permit others to solicit in my behalf, nor shall accept, a position which is occupied by another pathologist without first consulting with that pathologist.

2. I Shall Not Issue a report on preparations or materials from another pathologist’s laboratory or from institution which he serves, without immediately making every reasonable effort to inform that pathologist of the results of my examination.

3. I Shall Not Give or Receive either directly or by means of any subterfuge, a portion of fees for laboratory services either to referring physicians or from referral laboratories.

4. I Shall Not Compete for laboratory services on the basis of fees.

5. I Shall Not Issue reports to patient except when requested to do so by patient’s attending physician.

6. I Shall Not Participate directly or by means of any subterfuge, in an arrangement whereby an individual not regularly licensed to practice medicine is encouraged to operate a clinical or pathological laboratory.

7. I Shall Not Accept or continue to hold a position in any hospital or other medical institution, private or government, which does not conform to such relationships between the institution and the pathologist as may be approved by this Society.
Medical Technologists' Code of Ethics

As I enter the practice of Medical Technology, I shall:

Accept the responsibilities inherent to being a professional,

Uphold the law and shall not participate in illegal work,

Act in a spirit of fairness to all and in a spirit of brotherhood toward other members of the profession,

Accept employment from more than one employer only when there is no conflict of interest,

Perform my task with full confidence, absolute reliability and accuracy,

Share my knowledge and expertise with my colleagues,

Contribute to the advancement of the professional organization and other allied health organizations,

Restrict my praises, criticisms, views and opinions within constructive limits,

Treat any information I acquired in the course of my work as strictly confidential,

Uphold the dignity and respect of my profession and conduct myself with reliability, honesty and integrity,

Be dedicated to the use of clinical laboratory science to promote life and benefit mankind,

Report any violations of the above principles of professional conduct to the authorized agency and to the ethics committee of the organization,

To these principles, I hereby subscribe and pledge to conduct myself at all times in a manner benefitting the dignity of my profession.

Revised Code of Ethics: March 17, 1997
ADMINISTRATIVE ORDER
No. 2015-0053

SUBJECT: Implementing Guidelines on the Promotion and Marketing of Prescription Pharmaceutical Products and Medical Devices

I. RATIONALE/BACKGROUND

As provided by the 1987 Constitution, it is the State’s policy to protect and promote the right to health of the people and instill health consciousness among them (Sec. 15, Art. II). This includes the adoption of an integrated and comprehensive approach to health development which shall endeavor to make essential goods, health and other social services available to all the people at affordable cost (Sec. 11, Art. XIII), as well as the establishment and maintenance of an effective food and drug regulatory system (Sec. 12, Art. XIII), among others.

Article 108 of the Consumer Act of the Philippines (R.A. No. 7394) also declared as a policy of the State to protect the consumer from misleading advertisements and fraudulent sales promotion practices. The Food, Drug, Cosmetic and Medical Device Act (R.A. 3720 as amended by EO 175 and further amended by R.A. No. 9711) provides that it is State policy to ensure safe and good quality supply of food, drugs, and cosmetics, and to regulate the production, sale, and traffic of the same to protect the health of the people (Sec 2, Chapter II). The Generics Act of 1988 required all health professionals practicing both in public and private institutions, to write prescriptions using the generic name. The law further requires that any organization or company involved in the manufacture, importation, repacking, marketing and/or distribution of drugs and medicines shall indicate prominently the generic name of the product. Towards this end, Section 5 (o) of R.A. No. 9711 mandated the Food and Drug Administration (FDA), under the Office of the Secretary, Department of Health (DOH), to prescribe standards, guidelines, and regulations with respect to information, advertisements and other marketing instruments and promotion, sponsorship, and other marketing activities about health products. Section 4, Article V, Book II of the Implementing Rules and Regulation of R.A. No. 9711 likewise empowers the FDA to promulgate policies and directives that would rationalize promotional and marketing practices subject to existing laws on consumer protection.

To protect patient and consumers from the high out-of-pocket spending for medicines, Republic Act 9502, otherwise known as the Universally Accessible and Affordable Quality of Medicines Act of 2008, also authorized the Secretary of Health to promulgate policies and directives to rationalize promotional and
marketing practices on medicinal products and prohibit healthcare professionals from engaging in the promotion, advertisement or endorsement of drugs and medicines through all possible modes of communication.

The Philippines, as a member of the Asia-Pacific Economic Cooperation (APEC), supports APEC's thrust to promote the growth of small and medium enterprise (SME) which has been hampered by inappropriate business practices. These unethical business practices, especially in the area of product promotion imposed a significant market access barrier and high costs for SMEs in the health products sector. To address these problems, APEC has endorsed certain principles for codes of business ethics for players in the medical device and biopharmaceutical sectors, among others. These principles are specifically contained in two documents, to which the Philippine government is a signatory, namely: (a) The Kuala Lumpur Principles (KLP) Medical Device Sector Codes of Ethics; and (b) The Mexico City Principles (MCP) for Voluntary Codes of Business Ethics in the Biopharmaceutical Sector. The FDA has earlier issued Memorandum Circular 024 s. 2013 and Memorandum Circular 007 s. 2014 for Mexico City and Kuala Lumpur Principles, adopting both Codes for local application. To further strengthen the adoption of the Codes, Department Circular 0389 s. 2014 created an Inter-agency Committee to develop the Implementing Rules and Regulations on the Promotion and Marketing of Pharmaceutical Products and Medical Devices.

The Codes, being consistent with the current thrust of the Administration to uphold the values of integrity, accountability, transparency and good governance, attest the government's commitment to a sustainable implementation of anti-corruption measures and to exact the highest standards of integrity and professionalism in government processes and transactions as contained in the existing laws on graft and corruption, Anti-Graft and Corrupt Practices Act (RA 3019), and Code of Conduct and Ethical Standards for Public Officials and Employees (RA 6713).

To provide effective, safe and good quality drugs and medical devices, as well as to protect the people's rights to health, it is essential to maintain professionalism and high ethical standards in the interactions among the stakeholders in the pharmaceutical industry, including manufacturers, distributors, traders, health care professionals, health care related institutions and patients' organizations. Thus, consistent with the foregoing policies and pursuant to paragraphs (4), (9) and (10) of Section 3, Chapter 1, Title IX, Book IV of the Administrative Code of 1987 (EO No. 292), this Administrative Order is hereby promulgated.

II. OBJECTIVES

A. General Objective:

To ensure that medical decisions are made in the best interest of the patients, and that these are upheld by all stakeholders with the end goal of improving and promoting the rational use of prescription pharmaceutical products and medical devices and safeguarding patient rights and welfare.
B. Specific Objectives

To prescribe standards, guidelines, and regulations with respect to information dissemination, advertisements, promotion, sponsorship, and other marketing activities and instruments about prescription pharmaceutical products and medical devices with the end goal of improving and promoting their rational use, and safeguarding patient rights and welfare.

III. SCOPE AND COVERAGE

This Order shall apply to all natural and juridical persons and entities engaged in the dissemination or publication of information, advertisements and other marketing instruments and promotion, sponsorship, and other marketing activities of prescription pharmaceutical products and medical devices including their agents and/or their industry association.

This Order shall ensure that ethical interactions between industry and other stakeholders shall be guided by the principles embodied in the Mexico City and Kuala Lumpur Business Codes of Ethics: Healthcare and Patient Focus, Integrity, Independence, Legitimate Intent, Transparency, Accountability, Appropriateness and Advancement.

Further, this shall not contravene the provisions set in the Milk Code in the relation to promotion, sampling and marketing. These shall be covered by a separate IRR on promotion and marketing.

IV. DEFINITION OF TERMS

1. Conflict of Interest (COI) - shall mean a situation created when persons or entities in the public and/or private sectors that have personal, financial, or any other interest in the pharmaceutical and/or medical device industry, such as but not limited to, having existing ownership or investment therein, being an officer or member of the Board of Directors of a corporation (including its subsidiaries, affiliates and branches) or a partner in a partnership engaged therein and receiving any contribution there from. This includes receiving or accepting any offer or contribution there from.

2. Continuing Medical Education - Any action designed for or performed by a physician for the purpose of acquiring, maintaining, or upgrading knowledge, skills, or attitudes to improve the quality of the health care that the physician dispenses to the patient.

3. Disclosure - means the act of making known or revealing relevant material and information pertinent to the marketing and promotional practices of the pharmaceutical and medical device companies.

4. Events - means all promotional, scientific, or professional meetings, congresses, conferences, symposia and other similar events, (including, but not limited to advisory board meetings, visits to research or manufacturing facilities and planning or investigator meetings for clinical trials and non-intervention studies (each an "Event") organized or sponsored by or on behalf of a company.
5. Healthcare Organization (HCO) - means either a health care, medical or scientific associations, or organizations such as a hospital, clinic, university or other institutions or learned society whose business address place of incorporation or primary place of operation is in the Philippines or an organization through which one or more health professionals or other relevant decision-makers provide services.

6. Healthcare Professional (HCP) - means any member of the medical, dental, pharmacy or nursing profession or any other person who, in the course of his/her professional activities, may prescribe, recommend, purchase, supply, administer or dispense a health product accordingly.

7. Promotion - means the practice of giving value to a brand, product, or service to achieve specific marketing objectives. It includes the distribution of free/sample pharmaceutical products. It shall also refer to all informational and persuasive activities by manufacturers and distributors, the effect of which is to induce the prescription, supply, purchase and/or use of medicinal drugs.

8. Promotional material or Promotional aid - means a non-monetary item given to HCPs or an organization for a promotional purpose with minimum value which must be relevant to the HCP's work and not for personal benefit.

9. Third Party Conference - means a conference sponsored or conducted by or on behalf of a professional associate that is independent, of an educational or scientific or policy making nature and for the purpose of promoting scientific knowledge, medical advancement or delivery of effective health care.

V. IMPLEMENTATION MECHANISM

A. General Guidelines

1. The Department of Health, through the Office of the Secretary and the FDA shall issue appropriate policies, standards, and guidelines to further implement the provisions of this Order.

2. The Food and Drug Administration shall provide objective and consistent information, training and advice to health care professionals and pharmaceutical and medical device industries on their respective obligations in compliance with this Order as they become necessary.

3. Companies are enjoined to formulate their own Code of Ethics aligned with this Order.

B. Specific Guidelines

1. Interactions with Health Care Professionals (HCP)

a. Industry-HCP relationships shall be based on ethics and transparency to assure independence of HCP’s medical decisions and focus on protecting patients’ welfare.
b. Relationships between Company personnel and health care professionals shall encourage the development of a healthcare professional practice committed to patients' well being and based on truthful, accurate, and updated scientific evidence.

c. Prescription Pharmaceutical Products and Medical Devices (PPPMD) companies have the ethical obligation to ensure that their interactions with HCPs are in accordance with all applicable laws and regulations.

2. Promotional Information and Activities

a. Information provided by (PPPMD) manufacturers and distributors to health professionals regarding their products shall be restricted to evidence-based scientific data.

b. Promotional materials provided by industry to any HCP shall ensure the following:

1. Demonstrate the balance between risks and benefits
2. Comply with existing FDA and other pertinent regulations
3. Substantiate claims with up-to-date scientific evidence

c. Informational and educational materials, whether written, audio, or visual, dealing with the use of PPPMDs, shall include clear information on all the following points: (1) benefits and risks of the drug or device; (2) pharmacodynamics and pharmacokinetics of the drug; (3) indications and contraindications to use of the drug or device; (4) adverse effects and drug interactions.

d. Promotional or marketing materials of PPPMD companies using citations, quotes or statements lifted from medical literature, lectures, presentations, or similar sources of information shall not be changed, distorted or taken out of context.

The following claims and/or comments shall be prohibited:

1. One-sided information and any decisive statement based on inadequate or truncated evidence;
2. Superlatives, exaggerations and lines with hanging comparatives, without supporting data. E.g., “This product is better (e.g. Safety, efficacy, quality, and price) because....”;
3. Unsupported comments about competitors and their products;
4. Unspecified, un referenced claims about side effects, safety and efficacy.
Other Prohibited Words and Phrases are:

1. The word “new”, unless the product or indication has been available and generally promoted for less than twelve (12) months;
2. “Non-toxic”, and “no side effects”; and
3. Unspecified, unreferenced claims about safety, and efficacy without proper qualification

e. No PPPMD company shall employ or contract any HCP or health worker to promote, advertise or endorse any pharmaceutical product or medical device in mass media, print, audio visual display or social media.

f. PPPMD Company agents, including Medical Representatives shall not communicate directly to patients or their families in the promotion of their prescription pharmaceutical products

g. All advertising, promotional or other marketing materials, whether written, audio or visual, for products within the scope of this Order, may be subjected to a post-audit by the FDA and if any should be found to violate any FDA provisions, a cease and desist order and/or penalties and/or fines shall be issued by the FDA.

h. No government agency/facility shall be used for the purpose of promoting pharmaceutical or medical device products, nor be used for the display of products not within the scope of this Order or for placards or posters concerning such products except during scientific conventions when their facility is used as its venue.

i. Grants, scholarships, subsidies, support, consulting contracts, educational or practice-related items should not be provided or offered to an HCP in exchange for recommending and prescribing medicines, or otherwise in a manner that would interfere with the ethics and the independence of a health care professional’s respective practices.

3. Safety of Pharmaceutical and Medical Device Products

a. Pharmaceutical products and medical devices provided by Companies shall conform to high standards of quality, safety and efficacy as determined by the FDA.

b. Adverse events, whether serious or non-serious, arising from the use of these products, whether investigational or marketed shall be submitted to the FDA within specified timelines as provided in pertinent laws, rules and regulations in the Philippines.
4. **Symposia and Congresses**

1. Companies may support seminars, scientific meetings and third party conferences provided:

   a. The meals provided are modest;
   b. No entertainment that would incur expenses is provided during the entire duration of the activity;
   c. Conference Organizers shall make a written request to the PPPMD Company containing relevant information such as scientific content, attendees, duration and cost;
   d. The support provided is consistent with relevant guidelines set by this Order;
   e. The venue is appropriate and conducive to the scientific/educational objectives of the event. No extravagant venues are allowed, unless there is no other suitable venue in the locality where the event is to be held;
   f. All forms of support and activities are well documented;
   g. Attendees to such conference are legitimate or authorized; and
   h. Speakers shall disclose any potential or actual conflict of interest prior to topic presentation during the event.

2. PPPMD companies shall inform the FDA of any activities/events undertaken by the said company, whether or not the activities are in conjunction with any medical society/association, at least one month prior to holding of the said activity, if the activity involves more than 100 HCP participants. This is in order to enable the FDA to observe and monitor compliance with these guidelines.

3. The FDA designated or authorized officer and/or staff shall be allowed to do unannounced monitoring visits at conventions, symposia and conferences utilizing FDA funds.

5. **Informational Presentations by Company Representatives**

When presenting product information, PPPMD company representatives must provide scientific information of educational value to the HCP.

6. **Entertainment and Recreation**

   a. To ensure appropriate focus on education and informational exchange and to avoid the appearance of impropriety, PPPMD companies shall not provide any form of entertainment that would incur expenses for recreational items, such as tickets to the theater or sporting events, sporting equipment, or leisure or vacation trips, to any health care professional.

   b. Entertainment or recreational benefits shall not be offered, regardless of (1) the value of the items; (2) whether the Company engages the health care professional as a speaker or consultant, or (3) whether the entertainment or recreation is secondary to an educational purpose.
c. No stand-alone entertainment or other leisure or social activities shall be provided or paid for by companies during scientific meetings.

d. PPPMD Companies are prohibited from paying any travel sponsorship, meals, or other expenses of accompanying guests or family members of HCPs.

7. Educational Items and Gifts

a. Any item which does not have any direct patient benefit or is not related to the work of the HCP shall not be permitted.

b. Gifts or personal services and benefits unrelated to the work of the HCP shall not be provided by any PPPMD company representative to a health care professional or members of their families.

c. PPPMD companies may provide promotional aids to HCPs, provided these (a) are of modest value; and (b) are relevant to the practice of the health care professions or education of the patients.

d. PPPMD companies may occasionally provide items of medical utility to HCOs and HCPs such as textbooks, subscriptions to medical journals or anatomical models which benefit patients or serve a genuine educational function for the HCO or HCP. Items of medical utility should be modest.

8. Support for Continuing Professional Development (CPD)

The purpose of any continuing professional development activity shall be to provide additional and updated information to HCPs that can contribute to the improvement of patient care. PPPMD companies shall develop objective criteria for making CPD grants to ensure that programs funded are bona fide and quality educational programs. The financial support provided shall not be an inducement to prescribe to recommend a particular pharmaceutical product or medical device or any course treatment.

a. Industry sponsorship of HCPs to events involving foreign/local travel shall be allowed but subject to the following conditions:

1. The purpose of the event is to provide scientific or educational information;
2. The travel is justified because: (a) the event is held outside of the sponsored HCP's place/country of practice, and/or it makes greater logistical or security sense to hold the event in another location/country; or (b) the relevant resource or expertise that is the object or subject matter of the event is located outside of the sponsored HCP's place/country of practice.
3. The venue for such event is appropriate and conducive to the educational or scientific objectives of the conference; and
4. The selection of the HCPs should be unrelated to prescribing and sale of the PPPMD company's products.

b. The sponsoring PPPMD company, through its Medical Director, shall submit through the FDA website, events involving local and foreign travel containing the following information (Annex A):

1. The purpose/objectives of the travel, including the name, organizer, description, location and date of event;
2. The scope and estimated value of sponsorship to the event shouldered by the PPPMD company;
3. If the recipient is employed by the government, the sponsored HCP shall make a post travel report to his respective agency, including appropriate recommendations. Travel of government employees shall be in accordance with pertinent rules and regulations regarding such; and
4. The sponsorship for travel of HCPs attending events as legitimate participants shall only be for Economy class unless otherwise justified by health reasons or special needs of the HCP.

c. PPPMD companies shall act responsibly in terms of numbers of HCPs sponsored for international and/or local events and appropriateness of the cost based on prevailing government regulations for local travel or UNDP (Daily Subsistence Allowance) rate for international travel. A PPPMD company may sponsor a maximum of 20 HCPs to each legitimate overseas scientific educational event. The sponsorship to overseas events must consider equitable distribution of training opportunities to HCPs. Family members or guests of the HCPs are not allowed to be sponsored.

d. HCPs sponsored to overseas and local symposia, conventions or CPD events have the obligation to transfer knowledge in the medical community. An agreement to this effect should be made between the sponsoring PPPMD company and the HCP.

e. A PPPMD company may sponsor an HCP as a mere participant or delegate to a medical congress or convention involving international travel only once (1x) in any calendar year. Excluded from the scope of this provision are speakers, presenters, meeting officers (e.g., chairs, rapporteurs, organizers), clinical investigators, consultants or advisory board members; provided that the travel is justified in accordance with this Order and that there is a service agreement between the HCP and company in the case of contracted speakers, consultants, advisory board members, etc.
9. Samples

Samples may be provided to HCPs and HCOs provided that:

a. These are duly acknowledged by the HCP and HCO
b. Manufacturers and distributors shall not be permitted to give directly or indirectly, samples of prescription pharmaceutical products or medical devices to the general public or gifts of any sort to any member of health care professional’s immediate family. They shall not distribute samples of prescription products to anyone other than licensed physicians and dentist
c. In the case of substantial amounts provided for indigent patients, the recipient HCP and/or HCO shall execute a written statement that the samples shall be used for its intended purpose and shall not be used for financial gain.

10. Consultant and Speaker Arrangements

The engagement of consultant/s in medical conferences or scientific studies may be allowed provided there is a written contract which specifies the nature of services rendered and payment for such:

a. Criteria for consultant selection is based on identified need and expertise;
b. Contracting PPPMD company keeps a record of all transactions;
c. Compensation for said services is reasonable and reflect the fair market value for said services;
d. Disclosure of any potential or actual conflict of interest (Annex B) by the consultant or speaker must be made; and
e. Information is to be made public, if and when requested for legitimate purposes

11. Compliance Procedures and Responsibilities

a. All PPPMD companies shall comply with this Order. An effective compliance program must be established within the workplace which shall include the crafting of policies and procedures that promote compliance and which shall be documented in writing, approved and signed by the company head.

b. The market authorization holder (MAH) and the Certificate of Listing of Identical Drug Product (CLIDP) holder, through the highest ranking official of the PPPMD company i.e., the General Manager (or the equivalent) and the Compliance Officer, shall jointly be responsible for ensuring compliance with this Order.
c. To ensure that a PPPMD company's compliance program is effective, the company shall observe the 7 elements of effective compliance programs:

1. Implementing written policies and procedures;
2. Designating a compliance offices and compliance committee;
3. Conducting effective training and education;
4. Developing effective lines of communication;
5. Conducting internal monitoring and auditing;
6. Enforcing standards through well-publicized disciplinary guidelines; and
7. Responding promptly to detected problems and undertaking corrective action.

d. PPPMD companies shall provide the FDA with copies of their pro-forma contracts that they use when dealing with HCPs.

e. PPPMD companies shall see to it that the development and documentation of their internal compliance procedures that adhere to the APEC Principles and related Circulars and Orders issued by the FDA and DOH shall be observed within their organization.

12. Conduct of Training of PPPMD Company Representatives

a. Personnel employed as medical or sales representatives shall comply with existing Philippine Laws:

1. Be registered with the Professional Regulation Commission (Board of Pharmacy);
2. Be trained according to the standard training curriculum accredited by the Board of Pharmacy for all medical representatives, and as provided by law.
3. Have adequate training and sufficient scientific knowledge about their products to be able to give complete and accurate information in a responsible manner;
4. Report all current relevant safety information to the HCP regarding proper use of the product; and
5. Provide feedback to their office on reports submitted by the HCP on their experience with the product.

b. The practice of looking through prescriptions made by doctors at pharmacy outlets is a violation of patient confidentiality. Likewise, the offer and provision of financial rebates to doctors who make a specified quantity of prescriptions is unethical. Direct marketing of medical representatives with patients are strictly prohibited.
13. Public Sector Relationships and Procurement

a. The decision-making process by the Government on the issuance of permits and other authorizations, licensing, registration, pricing procurement, supply, and inclusion/exclusion in the national formulary and clinical guidelines shall adhere to the principles of integrity, transparency and public accountability.

b. PPPMD companies shall provide accurate and balanced information to the Government.

c. Government officials shall ensure that their relationships comply with government ethics rules or procedures based on the ethical standards of the Civil Service Commission (CSC) Republic Act 6713. The industry shall observe utmost compliance with and respect to the CSC Code of Conduct.

14. Clinical Trials

a. Any industry-funded research shall comply with the policies and general guidelines stipulated in pertinent DOH, FDA and Philippine National Health Research System (PNHRS) issuances and any future revisions. Once the research protocols are approved by Institutional Review Board/Ethical Review Boards (IRBs/ERBs) duly accredited by the FDA, these shall be forwarded to the FDA for their record and information. The FDA may conduct random inspections of the various institutions engaged in clinical trials to ensure compliance.

b. Researchers shall disclose that the activity is funded by a particular PPPMD company in their publication and any potential or actual conflict of interest in the conduct of the study shall be likewise stated.

c. For clinical studies wherein the Philippines is one of the trial sites, the industry may fund members of the research team to attend an international meeting/presentation of the study results and/or undergo training prior to the conduct of the study, subject to the rules on the symposia and congresses provided herein.

d. Moreover, PPPMD companies must respect the integrity of research activities and not fund, conduct, or use such activities as a means to disguise product promotion or prescription. All outcomes or results of researches conducted shall be forwarded to the FDA, regardless of whether the outcomes are favorable or not.

15. PPPMD Company Donations Charitable Purposes

a. PPPMDs intended for donation shall comply with the provisions of RA 3720 as amended and other FDA issuances.

b. All donated PPPMDs shall be subject to monitoring of its usage by FDA representatives and should not find their way to commercial outlets
(AO 54 s.2003; AO 0017 s. 2007). Furthermore, the donee shall execute an undertaking stating that the donated pharmaceuticals and devices will not be used for financial gain.

c. Nothing herein contained shall prevent donations from manufacturers and distributors of pharmaceutical products and medical devices intended for charitable, humanitarian or health purposes. Such donations shall not be made for promotional reasons, or be an incentive to prescribe, recommend or purchase any pharmaceutical product or medical device.

d. Donations may be given only to individuals or organizations with proper documentation of the amount (quantity and value) and nature of the donations made and due recognition from the recipient individual or organization of the support.

e. Medical missions shall not be used as a platform for promoting or advertising prescription pharmaceutical products or medical devices.

f. Any announcements (e.g. Billboards, posters, or flyers) to disseminate information regarding the conduct of the medical mission shall contain only the essential information pertaining to the mission (date, time and venue). Sponsoring PPPMD companies may include only their logos.

16. Patient Organization

a. PPPMD companies may give support to patient organizations, provided that the autonomy of such groups is upheld and the support is not intended to influence them to favor any particular product.

b. Patient Organizations shall work with the DOH and FDA in setting and abiding by their own ethical code of conduct. This is to ensure that any interaction with the industry shall be according to the core values of integrity, autonomy, and commitment to advance patient welfare and care.

c. Patient Organizations shall make a public disclosure of their funding sources.

17. Content of Promotional Materials - Refer to Annex C

18. Monitoring and Compliance

For the purposes of implementation of this Order, the DOH through the FDA shall be the lead agency responsible for the implementation and enforcement of this guideline.

PPPMD companies including their agents and/or their industry association are hereby ordered to strictly adhere to these guidelines and directives as well as strictly observe other relevant and existing FDA standards, rules and regulations.
19. Complaints/Information

a. Complaints/reports of violation shall be filed in writing with the FDA, and must include the information as prescribed in Section 3 Article IV, Book III of the Implementing Rules and Regulations of Republic Act No. 9711 or the FDA Act of 2009 (Annex D).

1. Reporting Forms and Information - Complaints/Information shall use the report form to report on alleged violations of this order.

2. Details on How to Report - Reports shall be submitted to the FDA through the Ethical Market Communications Unit of the FDA in its Alabang Office.

b. For other violations that are not within FDA jurisdiction, but with other offices of the DOH, it shall be filed in the Office of the Secretary of Health.

c. To assure quality of complaints, a PPPMD company filing a complaint against another PPPMD company shall pay a non-refundable filing fee to and shall post a bond with the FDA or the DOH in accordance with where the complaint is filed. The value of the filing fee and bond shall be determined by the DOH. Should the complaint be proven to be unsubstantiated, the bond shall be forfeited in favor of the FDA or the DOH as the case may be. No filing fee or bond shall be required from individual or patient organization complainants.

20. Sanctions

a. The FDA shall recommend the filing of the appropriate charges with the concerned government agency or appropriate court.

b. The FDA shall impose sanctions pursuant to RA 3720 as amended, and RA 9502, and RA 7394 as applicable.

c. The FDA shall post/publish the decision on its website.

VI. ROLES AND RESPONSIBILITIES

1. Department of Health

a. Ensure the effective and efficient implementation of this Order across the health sector.

b. Coordinate with relevant government agencies and sectors to ensure a whole of government approach in promoting ethical business practices and good governance in the provision of health products.

c. The Pharmaceutical Division shall monitor the impact of marketing and
promotional practices especially on the pricing of essential medicines and their rational use in the health sector as provided for in RA 9502.

d. Other Offices within the DOH i.e., Disease Prevention and Control Bureau (DPCB), Health Facilities and Services Regulatory Bureau (HFSRB), shall comply with the provisions of this Order and ensure its inclusion in any licensing requirement.

2. Food and Drug Administration

a. Ensure that the manufacture, packaging, import, export, distribution, marketing, sale and supply of health products are carried out according to specific standards of safety, efficacy and quality.

b. Participate and comply with international standards on the ethical promotion and marketing of health care products as applicable according to the national health care context to protect the welfare and safety of the Filipino public.

c. Provide an accessible and transparent platform for monitoring the progress of implementation and reporting cases of adherence and non-compliance to the set ethical standards.

d. Exert its authority to monitor the content of the information materials on health products disseminated to guarantee their accuracy, completeness and clarity to the public.

e. Enforce the rules and sanctions as contained in this Order in cases of non-compliance to the ethical standards.

f. Coordinate with and call on other relevant government agencies, international organizations, non-government organizations, HCOs, industry, other sectors for the effective implementation of these guidelines.

3. Industry Associations and Companies shall develop and implement their own standards/codes of ethics for health product promotion aligned with the principles and guidelines of this Order.

4. Health Care Professionals and Patient Organizations are enjoined to respect, abide and align their own Codes of Ethics to be consistent with this Order.

VII. SUPPLEMENTARY PROVISIONS

In case of doubt in the interpretation and implementation of the provisions of this Order, the same shall be liberally construed to carry out the policies of the State outlined herein and in favor of the best interest of the consumer.

Any other matters not provided in this guideline, but are consistent with the Mexico City and Kuala Lumpur Principles, if any, shall suppletorily apply subject to
existing laws.

The above notwithstanding, the DOH motu proprio or through the FDA, whenever it may deem necessary, shall not be precluded from further promulgating and prescribing standards, guidelines, and regulations with respect to information, advertisements, and other marketing instruments and promotion, sponsorship and other marketing activities about health products pursuant to its authority under R.A. No. 6675, R.A. No. 7394, R.A. No. 9502, R.A. No. 9711, or other relevant FDA-implemented laws.

VIII. REPEALING CLAUSE

All previous issuances which are inconsistent with the provisions of this Order are hereby repealed, amended or modified accordingly.

IX. SEPARABILITY CLAUSE

In the event that any provision or part of this Order is declared unauthorized or rendered invalid by any Court of law, those provisions not affected by such declaration shall remain valid and effective.

X. TRANSITORY PROVISION

This Order shall be fully implemented after one year from the date of its effectivity. Non-compliance shall warrant the imposition of applicable sanction/s without prejudice to the enforcement of order and regulations already existing and in effect prior to the full implementation of this Order.

XI. EFFECTIVITY

This Order shall take effect after fifteen (15) days following the completion of publication in two newspapers of general circulation

JANETTE P. LORETO-GARIN, MD, MBA-H
Secretary of Health
Annex A

POST TRAVEL REPORT

Program title:

Date / Duration:

Venue:

Delegation:

Objectives of the travel/ mission:

<table>
<thead>
<tr>
<th>Arrangement / Commitments</th>
<th>Resource requirements</th>
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<th>Timelines</th>
<th>Focal point / person</th>
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Learning / Knowledge gained:


Applicability to the Philippine situation:


### Annex B

**DECLARATION OF CONFLICT OF INTEREST**

1. **CURRENT FINANCIAL INTERESTS**
   - To your knowledge, do 1) you, your spouse, minor child, general partner, 2) organization in which you serve as an officer, director, trustee, general partner, or employee and/or 3) entity with whom you are negotiating or have any arrangement concerning prospective employment have any current involvement or financial link with the meeting/task issues (including competing companies)?

   a. **INVESTMENTS** (e.g., stocks, bonds, retirement plans, trust, partnerships, sector funds, etc.) □ NONE (If "none", skip to item b.)

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<tr>
<th>ESTABLISHMENT</th>
<th>TYPE OF INVESTMENT</th>
<th>OWNER (SELF, SPOUSE, ETC.)</th>
<th>NUMBER OF SHARES</th>
<th>CURRENT VALUE</th>
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<td>MORE THAN 15%</td>
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   b. **EMPLOYMENT** (Full or Part Time) (Current or Under Negotiation) □ NONE (If "none", skip to item c.)

<table>
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<tr>
<th>ESTABLISHMENT</th>
<th>RELATIONSHIP</th>
<th>POSITION IN FIRM</th>
<th>DATE EMPLOYMENT OR NEGOTIATIONS BEGAN</th>
</tr>
</thead>
</table>

   c. **CONSULTANT/ADVISOR** (Current or Under Negotiation) □ NONE (If "none", skip to item c.)

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<thead>
<tr>
<th>ESTABLISHMENT</th>
<th>TOPIC/ISSUE</th>
<th>AMOUNT RECEIVED</th>
<th>DATE FROM</th>
<th>DATE TO</th>
<th>RELATED TO LISTED PRODUCTS/INDICATIONS/ISSUES</th>
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   d. **CONTRACTS/GRANTS** (Current or Under Negotiation) □ NONE (If "none", skip to item e.)

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<tr>
<th>TYPE OF AGREEMENT (contract, grant)</th>
<th>PRODUCT UNDER STUDY AND INDICATIONS</th>
<th>AMOUNT OF REMUNERATION TO INSTITUTION</th>
<th>YOU</th>
<th>TIME PERIOD</th>
<th>SPONSOR*</th>
<th>YOUR ROLE**</th>
<th>AWARDSEE</th>
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*Government, Establishment, Institution, Individual

**Site Investigator, Principal Investigator, Co-Investigator, Employee, Partner, No Involvement, or Other**

**IF MORE SPACE IS NEEDED, PLEASE ATTACH ADDITIONAL PAGES.**
1. CURRENT FINANCIAL INTERESTS (Continued)
ed. PATENTS/ROYALTIES/TRADEMARKS: □ NONE (If "none", skip to item f.)

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<th>FOR</th>
<th>ESTABLISHMENT</th>
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f. EXPERT WITNESS (Last 12 Months or Under Negotiation): □ NONE (If "none", skip to item f.)

I appeared for or against the following listed establishment(s) and issue(s).

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<th>FIRM AND ISSUE</th>
<th>AMOUNT RECEIVED</th>
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g. SPEAKING/WRITING (Last 12 Months or Under Negotiation)

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<th>FIRM</th>
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2. PAST FINANCIAL INTERESTS
a. To your knowledge, do 1) you, your spouse, minor child, general partner, 2) organization in which you serve as an officer, director, trustee, general partner, or employee have any past involvement with the meeting/task issues:

   □ YES  □ NO  □ NOT TO MY KNOWLEDGE

b. If "Yes", describe involvement.

<table>
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<tr>
<th>FIRM/PRODUCT</th>
<th>FINANCIAL INVOLVEMENT</th>
<th>ROLE</th>
<th>DATES</th>
<th>RELATED TO LISTED PRODUCTS/INDICATIONS/ISSUES</th>
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IF MORE SPACE IS NEEDED, PLEASE ATTACH ADDITIONAL PAGES.
3. OTHER INVOLVEMENTS (Other Kinds of Relationships)  □ NONE (If “none”, skip to item 4.)

Using the list of products/firms/issues, identify anything that would give an “appearance” of a conflict which has not been disclosed above (e.g. involvement in a lawsuit, researcher initiated study, gift of research materials, etc.).

| [ ] |

4. CERTIFICATION STATEMENT

I, [ ] (name) [ ] (position and company or specialty) of the Republic of the Philippines, do hereby declare on my honor that the above information is true and complete, to the best of my knowledge. If there are any changes, I will notify you before the meeting/task.

My response contains [ ] pages.

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CONFIDENTIALITY STATEMENT

The primary use of this information is for review of the Food and Drug Administration, to determine compliance with applicable conflict of interest laws and regulations.

This confidential report will not be disclosed to any requesting person unless authorized by law.

Falsification of information or failure to file or report of information required to be reported is subject to disciplinary action by the FDA.

FOR FDA USE ONLY

<table>
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<th>SIGNATURE OF REVIEWING OFFICIAL</th>
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COMMENTS OF REVIEWING OFFICIAL

IF MORE SPACE IS NEEDED, PLEASE ATTACH ADDITIONAL PAGES.
Annex C

Content of Promotional Materials

1. Promotional content shall be consistent with the indications in the Certificate of Product Registration (CPR) and labeling materials as approved by the FDA.

2. General requirements of promotional material
   a. Any promotional material of pharmaceutical products (in any form of mass media) shall comply with the provisions set forth by Administrative Order 65 s. 1989, specifically under Section 3 on Guidelines on advertisement and promotions to implement the Generics Act of 1988, including any amendment thereto.
   b. Name and address of the Market Authorization Holder (MAH or product owner), importer, and/or distributor marketing the product.
   c. A brief profile of the essential product characteristics or succinct statement.
   d. Date of production (month/year) of the materials.

3. Abbreviated advertisements that contain only no more than a simple statement of indications and/or pharmacologic class to indicate the therapeutic category of the product shall include:
   a. Brand name and generic name of the product, consistent to the Generics Law of 1988 and the provisions set forth by Administrative Order 65 s. 1989 on Guidelines on advertisement and promotions including any amendment thereto;
   b. Name, logo and address of the Market Authorization Holder (MAH or product owner), distributor, and/or importer marketing the product;
   c. With a note starting with the phrase “Full prescribing information available from…”;
   d. Suggested Retail Price (SRP); and
   e. Related adverse events

4. Quotations
   a. Direct quotes shall be with the written permission from the original author and shall be used verbatim and in the context intended by the author.
   b. All claims shall represent the content of the substantiating sources accurately.
   c. Any information or quotation derived from publications shall properly cite the complete source using the following format: Name of the author, title of publication, name, volume and page of the journal, year of publication. The citation may be indicated as a footnote.

5. Data from clinical studies
   a. Research data, including those from clinical studies being used in promotional material, shall reflect fair and balanced information regarding risks and benefits of the product.
   b. Clearly mark in-vitro and animal tests data as such.
c. The following information to where the data can be shall include:
   1. Total number of subjects or patients involved (N values);
   2. Dosage regimen;
   3. Treatment period;
   4. Trial design;
   5. Clinical endpoints;
   6. Statistical significance; and
   7. Reference to related publications

6. Visuals, graphics and tables
   a. Visuals, such as graphics and tables, shall be consistent with the text to convey
      the information accurately.
   b. Graphs, tables and other visuals used shall be adequately cited. Copyright
      permission shall be obtained from the original authors, if the company cites these
      data in their promotional materials.

7. Unpublished data
   a. Unpublished data may be allowed if cited as “data on file”. Such data shall be
      available to HCPs on request. Before the promotional material is published, it
      must be available on hand and shall be kept for future reference.
   b. Prior to printing of promotional material, the complete length of publications and
      manuscripts for publication or in press shall be available on hand.

8. Claims
   a. All claims shall be accurate and substantiated from legitimate sources and be
      made available upon request.
   b. The use of phrases such as “Drug of first choice” or “The number 1 drug” shall
      be supported by up to date, sufficient and appropriate clinical evidence.
   c. Requirements for Comparative Claims:
      c.1. Claims properly supported by scientific data and in accordance with local
           regulations may be allowed;
      c.2. The use of adverse drug reaction data to compare two (2) drug products in
           promotional materials may be allowed to demonstrate a full, fair, and
           balanced comparison;
      c.3. Superiority claims may be allowed if supported by competent (measuring up
           to all requirements) and well-controlled clinical trials; and
      c.4. Claims related to difference in efficacy between drugs may be allowed if it is
           clinically relevant and statistically significant (p ≤ 0.05).

*Reference: Novartis Pharma Principles and Practices for Professionals (NPP), 11.2.4-11.2.12
Annex D

FDA Report/Complaints Handling Procedure

1. Complaints of violation of this Order shall be filed with the FDA. All complaints shall be in writing and must include the following in accordance with Sec. 3 Art. IV, Book III of the IRR of RA 9711:

1.1 Name and complete address of the Reporter/Complainant

1.2 Date and Time of Violation

1.3 Name of the Company in violation

1.4 Summary of the report/complaint describing the nature, date and place of the violation, the Section of this Order that was violated and other relevant information

1.5 Copies of the materials/photos or other evidence of violation

1.6 The Report/Complaint shall be notarized.

Note: If report/complaint is from industry, it shall be signed by a legal officer and supported with an affidavit.

2. Company associations may receive and resolve complaints between or among its members, provided:

2.1 It submits to FDA its constitutional documents including an up-to-date list of its member organizations

2.2 It establishes a committee for resolving such complaints composed of independent members/experts that are not employed, affiliated or involved in business transactions (directly or through his/her organization) with any of its member companies.

2.3 It shall submit to FDA copies of its decision together with the relevant attachments for filing and posting at the FDA website as deemed applicable by FDA.
Commencement of Action

Ways of Initiating Action or Filing a Complaint (Sec. 1 of Art. IV)
1. filing of complaint or petition by party
2. motu proprio (FDA initiated)
3. referral by Consumer Arbitration Officer or other government officers
4. Anonymous complaints/petitions/requests for confidentiality

Where to File? (Sec. 1 of Art. II- VENUE)
- FDA Central Office or
- Regional Field Office

Summons (Sec. 1 of Art. V)
Within 3 days from initiation of action

Answer (Sec. 1 of Art. VI & VII)
Within 5 days from service of summons

Preliminary Conference (Sec. 2 of Art. VII)
Within 5 days from receipt of Answer

Hearing (Sec. 1 of Art. VIII)
Within 15 days from Preliminary Conference
- in lieu of formal hearing, may require parties to submit position paper/ memorandum (Sec. 1 of Art. IX & X)

Submission for Resolution (Sec. 1 of Art. XI)
Within 15 days from receipt of the last pleading required

Appeal to Secretary of Health (Sec. 1 of Art. XII)
Within 15 days from receipt of the decision of the Director-General

Decision by the Director General (Sec. 4 of Art. XI)
Within 15 days from receipt of the records

RA 9711 FLOWCHART OF UNIFORM RULES OF PROCEDURE

Note: Dotted lines show that the FDA Legal Office is already taking action to the case.
SUSPECTED VIOLATION REPORT FORM

DATE: ______________________

FULL NAME OF REPORTER: __________________________

ADDRESS OF REPORTER: ____________________________

_________________________________________________

CONTACT INFORMATION: E-MAIL: ______________________ MOBILE/LANDLINE: ______________________

Time and Date of Suspected Violation: ______________________

SUMMARY OF THE OBSERVATIONS (PLEASE INDICATE NATURE OF COMPLAINT, DATE & PLACE OF VIOLATION, SECTION OF THE ORDER BEING VIOLATED, NAME OF VIOLATING COMPANY & OTHER RELEVANT INFORMATION):

_________________________________________________

_________________________________________________

_________________________________________________

_________________________________________________

_________________________________________________

Signature Over Printed Name of Reporter

With supporting affidavit of complainant, as prescribed in the IRR of RA 9711
(Note: Please attach copies of the materials/photos or other evidence of violation.)

Findings of inspection/investigation by the FDA: