



Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

DEC 21 2015

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 tall 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, unreferenced 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 or 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

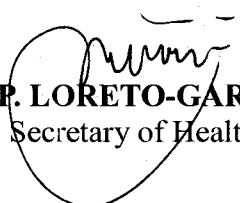
In the event that any provision or part of this Order is declared unauthorized or rendered invalid by any Court of law, those provisions not affected by such declaration shall remain valid and effective.

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:

Arrangement / Commitments	Resource requirements				Timelines	Focal point / person
	Personnel	Funding	Technical assistance	Equipment		

Learning / Knowledge gained:

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Applicability to the Philippine situation:

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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.)**

ESTABLISHMENT	TYPE OF INVESTMENT	OWNER (SELF, SPOUSE, ETC.)	NUMBER OF SHARES	CURRENT VALUE	CHECK % NET WORTH		
					LESS THAN 5%	5-15%	MORE THAN 15%

b. EMPLOYMENT (Full or Part Time) (Current or Under Negotiation) ☐ **NONE (If "none", skip to item c.)**

ESTABLISHMENT	RELATIONSHIP	POSITION IN FIRM	DATE EMPLOYMENT OR NEGOTIATIONS BEGAN

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

ESTABLISHMENT	TOPIC/ISSUE	AMOUNT RECEIVED	DATE FROM	DATE TO	RELATED TO LISTED PRODUCTS/INDICATIONS/ISSUES

d. CONTRACTS/GRANTS (Current or Under Negotiation) ☐ **NONE (If "none", skip to item e.)**

TYPE OF AGREEMENT (contract, grant)	PRODUCT UNDER STUDY AND INDICATIONS	AMOUNT OF REMUNERATION TO		TIME PERIOD	SPONSOR*	YOUR ROLE**	AWARDEE	RELATED TO LISTED PRODUCTS/INDICATIONS/ISSUES
		INSTITUTION	YOU					
								<input type="checkbox"/> YES <input type="checkbox"/> NO
								<input type="checkbox"/> YES <input type="checkbox"/> NO
								<input type="checkbox"/> YES <input type="checkbox"/> NO
								<input type="checkbox"/> YES <input type="checkbox"/> NO

*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)

e. PATENTS/ROYALTIES/TRADEMARKS ☐ NONE (If "none", skip to item f.)

FOR	ESTABLISHMENT	RELATED TO LISTED PRODUCTS/INDICATIONS/ISSUES	IF "YES", EXPLAIN BELOW AND INDICATE INCOME RECEIVED NUMBER OF SHARES
		<input type="checkbox"/> YES <input type="checkbox"/> NO	
		<input type="checkbox"/> YES <input type="checkbox"/> NO	
		<input type="checkbox"/> YES <input type="checkbox"/> NO	

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).

FIRM AND ISSUE	AMOUNT RECEIVED	RELATED TO LISTED PRODUCTS/INDICATIONS/ISSUES	IF "YES", EXPLAIN BELOW
		<input type="checkbox"/> YES <input type="checkbox"/> NO	
		<input type="checkbox"/> YES <input type="checkbox"/> NO	
		<input type="checkbox"/> YES <input type="checkbox"/> NO	

g. SPEAKING/WRITING (Last 12 Months or Under Negotiation)

FIRM	TOPIC/ISSUE	AMOUNT RECEIVED		DATES	RELATED TO LISTED PRODUCTS/INDICATIONS/ISSUES
		HONORARIUM	TRAVEL		
					<input type="checkbox"/> YES <input type="checkbox"/> NO
					<input type="checkbox"/> YES <input type="checkbox"/> NO
					<input type="checkbox"/> YES <input type="checkbox"/> NO

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.

FIRM/PRODUCT	FINANCIAL INVOLVEMENT	ROLE	DATES	RELATED TO LISTED PRODUCTS/INDICATIONS/ISSUES
				<input type="checkbox"/> YES <input type="checkbox"/> NO
				<input type="checkbox"/> YES <input type="checkbox"/> NO

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.

SIGNATURE

DATE

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

SIGNATURE OF REVIEWING OFFICIAL

DATE

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($p \leq 0.05$).

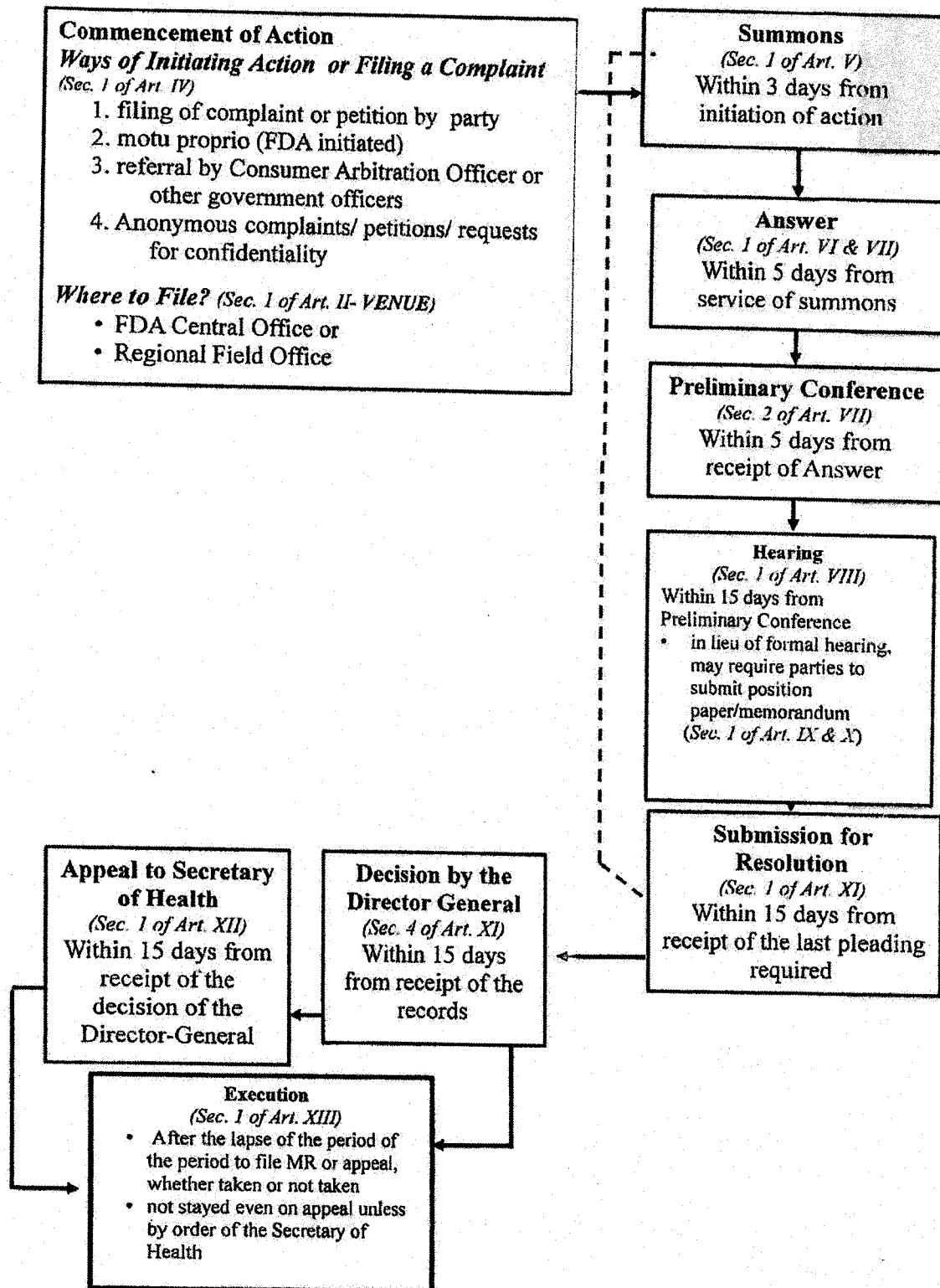
*Reference: Novartis Pharma Principles and Practices for Professionals (NP4), 11.2.4-11.2.12

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.



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: