# PAMDRAP CODE OF ETHICS


Philippine Association of Medical Device Regulatory Affairs Professionals

Code of Ethics

Revision 1.0

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www.pamdrap.org

## Message From the Board

When the founders of the Philippine Association of Medical Device Regulatory Affairs Professionals convened to form PAMDRAP in 2011, they envisioned an organization that will uplift the Philippine medical device industry especially in the field of medical device regulations. Since then, PAMDRAP has helped members to ensure compliance with new regulations by serving as the industry voice to the FDA and by conducting training sessions in cooperation with the FDA.

With the implementation of the regulation on ethical business practices in the healthcare industry and the increasing growth of the medical device industry, the PAMDRAP Board of Directors has decided that this is an opportune time to further contribute to the medical device industry in the Philippines beyond regulatory compliance by adopting our own PAMDRAP Code of Ethics and aligning with the regulation. It is an honor to present this Revised Code to you now.

We trust that wit this tool and with your support, we will indeed contribute to the upliftment of the medical device industry.

*- BOD, 2016-2017*

## Contents

## 1. PURPOSE

1.1 The purpose of this Code is to provide guidance to PAMDRAP members and member companies to facilitate ethical interactions between companies, healthcare professionals (HCPs), and government officials in the Philippines.

1.2 This Code will also help PAMDRAP members and member companies to comply with the guidelines of the Philippine Food and Drug Administration on ethical marketing practices.

1.3 Ethical interactions between companies, HCPs, and government officials provide numerous benefits, such as:

(a) ensuring that medical decision-making is made in the best interest of the patient;

(b) increasing public confidence in the medical device and diagnostics industries;

(c) enhancing patient access to the safe and effective use of medical technologies by ensuring appropriate training of HCPs by companies;

(d) promoting innovation and the ongoing development of medical technologies through legitimate and transparent collaboration; and

(e) facilitating open and transparent business environments free from the high costs of corruption, enhancing the ability of companies to participate in global markets.

## 2. GENERAL PRINCIPLES

2.1 This Code is based upon the following general principles:

(a) Advancement – Company relationships with HCPs and government officials must be for the purpose of advancing medical technology, innovation and patient care.

(b) Integrity – Companies must interact with HCPs and government officials in an honest, truthful, and fair manner.

(c) Independence – Companies may not provide anything of value to improperly influence HCPs and government officials from making medical decision that are based on the best interests of the patients.

(d) Appropriateness – Interactions must be modest and/or reflect fair market value, and be for legitimate purposes.

(e) Transparency – Companies must be transparent regarding significant financial relationships with HCPs and government officials.

2.2 To the extent that any provision of this Code conflicts with a provision of a law, regulation, company policy, or local medical technology industry code of ethical conduct, companies shall comply with the provisions that have the strictest requirements or highest ethical standards.

**3. DEFINITIONS**

In this code:

a. *Companies* mean organizations that develop, manufacture, import, distribute, market or sell medical technologies in the Philippines.

b. *Demonstration Products* mean products that are used for training of HCPs or for patient education.

c. *Evaluation Products* mean products provided for human use, either as free samples of single-use products, or loans of reusable products or capital equipment.

d. *Food and Drug Administration (FDA)* means the governing body for medical technologies in the Philippines.

e. *Healthcare professionals (HCPs)* include individuals and entities who purchase, lease, recommend, use or arrange for the purchase or lease of, or prescribe company medical technologies. These include both clinical and non-clinical individuals who make product-related decisions of the type described above and anyone with material influence over purchasing decisions. Examples of non-clinical individuals are purchasers and service engineers.

f. *Medical technologies* means products, technologies and related services and therapies used to diagnose, treat, monitor, manage and alleviate health conditions and disabilities. These include Medical Devices as defined under the Philippine Republic Act 9711, which states:

> Medical devices means any instrument, apparatus, implement, machine, appliance, implant, in-vitro reagent or calibrator, software, material, or other similar or related article intended by the manufacturer to be used alone, or in combination, for human beings for one or more of the specific purpose(s) of diagnosis, prevention, monitoring, treatment or alleviation of disease; diagnosis, monitoring, treatment, alleviation of, or compensation for an injury; investigation, replacement, modification, or support of the anatomy or of a physiological process; supporting or sustaining life; preventing infection; control of conception; disinfection of medical devices; and providing information for medical or diagnostic purposes by means of in-vitro examination of specimens derived from the human body. This device does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means but which may be assisted in intended function by such means.

h. *Government officials* include any government employee or representative, elected official or candidate, or employee of a state-owned business. The term government official shall include, but not be limited to, personnel of the Department of Health, all Customs Offices, Tax Offices, and health-related statutory authorities; anyone employed in hospitals affiliated with public educational institutions; and anyone employed in government operated health care facilities or those otherwise substantially involved with a governmental entity.

## 4. CONSULTING ARRANGEMENTS WITH HEALTHCARE PROFESSIONALS

4.1 Companies may engage HCPs to provide services that support research and development to advance medical science, develop new technologies, improve existing products and services, educate on the safe and effective use of company products or enhance the quality and efficacy of patient care.

4.2 This section also applies to contract research organizations for post marketing activities, clinical documentation, and other related activities.

4.3 Consulting arrangements between companies and HCPs must comply with the following:

a. a legitimate need and purpose for the services is identified in advance;
b. only the number of HCPs reasonably needed to perform the services are engaged;
c. HCPs are selected based on their qualifications to perform the services and are not on the basis of the volume or value of business generated or potentially generated by them;
d. compensation paid to a healthcare professional consultant must be consistent with fair market value for the services actually performed;
e. compensation is paid after the services have been performed and upon sufficient evidence of performance of services (retainer fees or other advance payments are not permitted);
f. compensation is paid either by cheque or electronic bank transfer and not by cash;
g. the services and compensation to be paid (if any) are documented in a written agreement in advance of the services being performed; and
h. consulting arrangements should be disclosed in advance and in writing to the HCP consultant's institution or employer, unless applicable laws, regulations or institutional rules specifically require disclosure to a different body, in which case disclosure should be made in accordance with the applicable laws, regulations or rules.

4.4 When it is necessary for the HCP consultant to travel in order to perform the services, companies may pay for or reimburse the reasonable travel, accommodation and meal expenses, provided that:

a. the expenses are limited to those that are necessary for the HCP to perform the services;
b. no expenses are paid for spouses or other guests accompanying the HCP;
c. whenever possible, companies make travel bookings directly on behalf of the HCP, rather than providing reimbursement to the HCP;
d. when direct bookings are not possible, reimbursement is only made for actual and appropriate costs incurred, and upon submission of original receipts or other adequate proof of payment;
e. reimbursement is made either by cheque or electronic bank transfer and not by cash; and
f. companies must not fund the HCP consultant's vacation or other personal activities such as private side trips.

4.5 Companies must provide FDA with copies of their proforma contracts that they use when dealing with HCPs.

## 5. THIRD PARTY EDUCATIONAL CONFERENCES

5.1 A third party educational conference is a conference sponsored or conducted by or on behalf of a professional association 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 healthcare.

5.2 Companies may support such conferences through grants to conference organizers or institutions to support individual attendance to the conference, or through other appropriate methods, provided that:

a. such support preserve the independence of medical education and not be used as a means of inappropriate inducement;
b. grants be made only following a written request from the conference organizer or institution and include sufficient information to allow the company to evaluate the scientific and educational merit of the conference;
c. the conference venue and agenda are appropriate. The support is consistent with relevant guidelines established by the conference organizer, institution and any accreditation body;
d. the conference organizer independently controls and is responsible for the selection of program content, faculty, educational methods, and materials;
e. the funding provided is proportionate to the overall costs of the conference and is consistent with prevailing guidelines;
f. companies do not directly pay for, or reimburse, the expenses of any individual HCP delegate to attend the conference and grants must not inappropriately benefit individual HCPs or provide for side trips, recreation, entertainment or lavish meals or accommodations;
g. grant arrangements are appropriately documented and reported to FDA if applicable;
h. companies sponsor a maximum of 20 HCPs to each legitimate overseas scientific educational event and must consider equitable distribution of training opportunities to HCPs;
i. companies incorporate a Service Engagement as a post-training requirement for the HCP to transfer the knowledge obtained from the event to the medical community; and
j. companies sponsor an HCP as a mere participant or delegate to a medical congress or convention involving international travel only once a year.

5.3 Where consistent with the conference organizer's guidelines, Companies may sponsor or organize appropriate meals in connection with conferences, provided that such meals are:

a. modest in cost;
b. do not include entertainment or recreational activities;
c. subordinate in time and focus to the scientific or educational purpose of the conference; and
d. only provided to Healthcare Professional attendees of the conference.

5.4 Companies may sponsor advertisements and lease booth space for company displays at conferences.

5.5 Companies may also sponsor satellite symposia in conferences and provide scientific content, faculty, venue, and meals for these symposia provided that the arrangements are disclosed in writing in all materials relating to the satellite event. If HCP consultants are involved in these symposia, the provisions relating to HCP consultants also apply. In addition, speakers shall disclose any potential or actual conflict of interest prior to topic presentation during the event.

5.6 Companies shall inform the FDA of any activities/event undertaken at least one month prior to holding of said activity, if the activity involves more than 100 HCP participants.

## 6. COMPANY-SPONSORED TRAINING AND EDUCATIONAL MEETINGS

6.1 Companies may provide training and education to HCPs on the safe and effective use of company products, including "hands -on" training sessions, cadaver workshops, wet lab sessions, live surgeries, lectures, and presentations. These also include trainings organized by the company regulatory affairs associates such as medico-vigilance and product trainings.

6.2 Companies may provide reasonably-priced meals in connection with training and education meetings.

6.3 Training and educational meetings must:

a. be held in a location (e.g. town or city) that is logistically sensible considering the location of the majority of participants and those providing the educational learning, and is not considered primarily as tourist or resort location;
b. be held in appropriate venues such as the HCP's premises, company's premises, clinical, laboratory, educational or conference facilities (including hotel meeting rooms) conducive to effective learning;
c. be conducted by qualified personnel, which may include sales personnel with adequate technical expertise;
d. follow a robust educational agenda with limited but reasonable time for breaks and meals; and
e. not include entertainment or other inappropriate activities.

6.4 When it is impractical or inefficient to provide training at or close to a HCP's place of business (such as for plant tours or demonstrations of non-portable equipment), companies may pay the reasonable travel and accommodation costs, provided that:

a. the costs are limited to those that are necessary for the HCP to attend the training;
b. no costs are paid for spouses or other guests that are not legitimate attendees in their own right;
c. whenever possible, companies make travel bookings directly on behalf of the HCP, rather than providing reimbursement to the HCP;
d. when direct bookings are not possible, reimbursement is only made for actual and appropriate costs incurred, and upon submission of original receipts or other adequate proof of payment;
e. reimbursement is made either by cheque or electronic bank transfer and not by cash; and
f. companies must not fund HCP's vacation or other personal activities, such as private side trips.

6.5 Companies shall provide information required by FDA in relation to the sponsorship of the HCP.

## 7. MEALS PROVIDED DURING BUSINESS MEETINGS

7.1 Company representatives may meet from time to time with HCPs to discuss product features, conduct contract negotiations, or discuss sales terms. Such meetings are subject to the following rules:

a. meetings should generally occur at or near the HCP's place of business, although occasionally such discussions may take place at another mutually convenient location, provided it is conducive to the business discussion;
b. meals must be modest and incidental to the business discussion;
c. entertainment should not be provided; and
d. expenses should not be paid for spouses or other guests of HCPs who do not have legitimate business purpose in attending the meeting.

## 8. EDUCATIONAL ITEMS

8.1 Companies may occasionally provide items to HCPs that benefit patients or serve as educational tools for HCPs. Items that are not useful to the HCP's practice are inappropriate.

8.2 Educational items should be modest in cost, as determined by local standards, and should not be provided with excessive frequency.

8.3 Certain permissible educational items, such as textbooks and anatomical models, may be higher in cost but nonetheless, should not be extravagant.

## 9. GIFTS AND ENTERTAINMENT

9.1 Gifts are items that are provided to individual HCPs that do not fit into any of the categories set out in this Code. Gifts include cash, gift cards, food, wine or spirits, gift baskets, flowers or any type of branded promotional items.

9.2 Companies must not provide gifts to HCPs even if the item is of minimal value.

9.3 Companies must not provide, organize or pay for recreational or entertainment activities for HCPs, including (without limitation) sporting events, tourist, cultural or artistic activities, or leisure activities.

## 10. GRANTS AND DONATIONS

10.1 Companies may provide research, educational and charitable grants and donations provided that the company:

a. adopts objective criteria for providing grants and donations that do not take into account the volume or value of purchase made by, or anticipated from, the grant recipient or affiliated HCPs;
b. implements appropriate procedures to evaluate grant and donation requests against those objective criteria and to ensure that they are not used as a condition of purchase of the Company's products or to improperly obtain any other form of advantage;
c. ensures that sales representatives do not control or unduly influence decisions around grants and donations although they may provide input to help evaluate the suitability of a proposed program or recipient;
d. does not provide grants for inappropriate activities, such as holiday parties or entertainment activities;
e. does not link the grant or donation directly or indirectly to the purchase of medical technologies;
f. provides the grant or donation in response to a written request from a bona fide organization or institution;
g. provides the grant or donation to the requesting institution or organization and not to individual HCPs; and
h. documents the grant or donation provided, including the acknowledgement of receipt by the authorized representative of the requesting institution or organization.

## 10. GRANTS AND DONATIONS

10.2 In addition to the rules set forth above, the following rules apply to the particular types of grants and donations specified:

a. Charitable Donations (monetary or in-kind):

(i) Companies may make monetary and in-kind donations to support bona fide charitable organizations and missions and non-profit organizations for charitable purposes, such as supporting indigent care, patient education, public education or the sponsorship of events where the proceeds are intended for charitable purposes.

(ii) In rare instances, donations may be made to individuals engaged in genuine charitable activities for the support of a bona fide charitable mission, but it is the obligation of the Company providing such donation to ensure that the mission is bona fide and that such individual will not personally benefit, directly or indirectly, from the donation provided.

b. Educational Grants:

(i) Companies may provide grants to support legitimate educational purposes, such as the medical education of HCPs, or medical students, residents, and fellows, and education of patients and the public about important healthcare topics.

(ii) Grants may not exceed the value necessary to achieve the educational purpose.

c. Research Grants:

(i) Companies may provide research grants to support independent medical research with scientific merit for the purpose of advancing scientific and clinical information, improving clinical care, promoting improved delivery of healthcare, or to otherwise benefit patients.

(ii) Sponsored research should have well-defined objectives and milestones that are documented in a research protocol or similar document.

(iii) Payments should only be made upon evidence of satisfactory completion of the research activities or at agreed milestones as documented in the research protocol.

(iv) Company-initiated or directed research involving a company's medical technologies is not covered by this section and should be evaluated under the provisions addressing consulting arrangements.

10.3 Donations in the form of FDA-certified medical technology products must be duly acknowledged by the HCP and healthcare organization. In addition, the HCP and/or healthcare organization shall execute a written statement that the products shall be used for its intended purpose and shall not be used for financial gain.

10.4 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 companies may include only their logos.

## 11. DEMONSTRATION AND EVALUATION PRODUCTS

11.1 Companies may provide medical technologies to HCPs free of charge for demonstration and evaluation purposes, provided that:

a. they are not given or intended as an improper inducement;
b. demonstration products should be marked “not for human use” or otherwise to indicate that they are solely for demonstration purposes;
c. evaluation products are provided in quantities (or for a duration) that is reasonably determined to enable adequate evaluation by the HCP;
d. evaluation products should be appropriately disclosed and documented and acknowledged by the HCP and healthcare organization;
e. companies should ensure that loaned products are retrieved or returned if not purchased at the end of the evaluation period; and
f. companies shall not give directly or indirectly, demonstration or evaluation products to the general public.

## 12. APPLICABILITY TO GOVERNMENT OFFICIALS

12.1 The foregoing sections also apply to government officials whenever the circumstances are applicable and/or allowed by law or local regulations.

## 13. PROMOTIONAL INFORMATION AND ACTIVITIES

13.1 Information provided by companies regarding their products shall be restricted to evidence-based scientific data.

13.2 Promotional materials provided by companies shall:

a. Demonstrate balance between risks and benefits
b. Comply with existing FDA and other pertinent regulations
c. Substantiate claims with up-to- date scientific evidence

13.3 Companies shall not employ or contract any HCP or health worker to promote, advertise or endorse their product in mass media, print, audio visual display or social media.

13.4 Companies shall not use government agency/ facility to promote products except during scientific conventions when their facility is used as venue.

13.5 Company agents shall not communicate directly to patients or their families in the promotion of their products.

## 14. SAFETY OF MEDICAL TECHNOLOGIES

14.1 Medical technologies provided by companies shall conform to high standards of quality, safety and efficacy as determined by FDA.

14.2 Adverse events arising from the use of medical technologies shall be submitted to the FDA within the specified timelines as provided in pertinent laws, rules and regulations (if regulations exist or if applicable).

## 15. CLINICAL TRIALS

15.1 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.

15.2 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.

## 16. GUIDANCE TO ENSURE EFFECTIVE CODE IMPLEMENTATION

16.1 In order to ensure effective implementation of Code principles, each company may take the following concrete steps:

a. appoint a senior executive responsible for oversight of the company's compliance with this Code;
b. adopt practical, useful, and meaningful policies, guidance and tools intended to ensure compliance with the Code;
c. provide effective and ongoing training and education on the Code and on company policies implemented to ensure Code compliance;
d. ensure that senior management and the company's board of directors or other governing body have expressly committed to support the Code;
e. institute appropriate internal monitoring and auditing mechanisms;
f. create safe mechanisms for, and encourage, employees who raise concerns; and
g. require that third party intermediaries (including consultants, distributors, sales agents, and brokers) that may interact with HCPs in connection with the company's medical technologies agree to comply with this Code; and
h. keep updated on new regulatory requirements.

## RESOURCES:

www.businessethics.apec.org

http://www.fda.gov.ph/industry-corner/emc-ethical-marketing-communications

www.pamdrap.org

## REFERENCES:

APEC KL Principles—http://mddb.apec.org/documents/2011/MM/SMEMM/11_smemm_009.pdf

FDA Administrative Order No. 2015-053

*This Code was made possible by all the members who approved the code, the Committee on Ethics, and the PAMDRAP Board of Directors 2016-2017.*

*A code of ethics offers significant benefits to the community, the industry and the member companies.*

*For PAMDRAP, the most valuable outcome of having our own code of ethics is that it will enhance the image of the medical device industry and build our reputation with regulators.*

*Ultimately, companies that go beyond compliance and bring transparency to business processes, and enable ethical sales and marketing operations will grow their businesses as they fill the role of preferred distributors (or manufacturers) for healthcare collaboration and transform themselves into industry leaders.*

*- J. Gulle, Chair, Committee on Ethics*

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