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Philippine Chamber of the Pharmaceutical Industry, Inc.

PCPI CODE of ETHICS 2014

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Page 1 of 27



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Philippine Chamber of the Pharmaceutical Industry, Inc.

I. INTRODUCTION

The Philippine Chamber of the Pharmaceutical Industry, Inc., hereinafter referred to as PCPI, is an industry organization composed of Filipino pharmaceutical manufacturers and traders/distributors. The PCPI mission is to enable the Philippine pharmaceutical industry to lead. The vision is a globally competitive Filipino pharmaceutical industry.

It was established in March 2004 from the merger of 4 national pharmaceutical organizations: Chamber of Filipino Drug Manufacturers and Distributors, Inc. (CFDMD), Association of Drug Industries of the Philippines (ADIP), Filipino Drug Association (FIDA), and the Association of Philippine Pharmaceutical Manufacturers (APPMAN).

The Code of Business Ethics is formulated to guarantee that the Filipino patient will have increasing access to safe, quality, efficacious pharmaceutical products. It espouses transparency in dealing with the health sector stakeholders. This will eventually lead to a more level playing field in the Philippine pharmaceutical industry.

The Code uses as template and basis the 2011 Mexico City Principles for Voluntary Codes of Business Ethics in the Biopharmaceutical Sector, as developed and



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Philippine Chamber of the Pharmaceutical Industry, Inc.

promulgated by the Asia-Pacific Economic Cooperation (APEC) initiative. This also acknowledges the following materials as reference: Code of Pharmaceutical Marketing Practices of the Pharmaceutical-Healthcare Association of the Philippines (PHAP) and the Code of Ethics of the former Chamber of Filipino Drug Manufacturers and Distributors, Inc. (CFDMD).

The Code was designed as a model of ethical business behaviour for PCPI member companies. The Code is meant to evolve in time to address the changing business environment.

II. OPERATION OF THE CODE

PCPI adopts this Code as the Chamber's organizational values. PCPI encourages member companies to adopt the Code and translates these into company values, policies and procedures.

It will create a Committee on Ethics chaired by the incumbent PCPI President with the Vice Presidents of the marketing and manufacturing sectors as members. The ethics committee will arbitrate "Business Ethics" issues between its members. The committee will exert all effort to resolve the issues amicably. In the event a resolution



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Philippine Chamber of the Pharmaceutical Industry, Inc.

cannot be resolved, PCPI will escalate the resolution of the complaint to relevant government institutions.

III. COMMITMENTS

The PCPI is committed to making available affordable, safe, quality, efficacious pharmaceutical products to Filipino patients. As PCPI member companies provide such pharmaceutical products, these companies also comply with the laws and regulations of the Philippines governing the manufacture, sale and distribution of pharmaceutical products. Beyond that, the companies strive to follow the highest ethical standards in dealing with industry stakeholders: healthcare professionals, government officials, suppliers and vendors.

PCPI is committed to promote ethical and fair practices and friendly competition among its members and other companies within the Philippine pharmaceutical industry.

PCPI is committed to encourage member companies to provide objective, accurate and balanced information about their pharmaceutical products to healthcare professionals. This encompasses a commitment to education and training of the company's representatives and agents.



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Philippine Chamber of the Pharmaceutical Industry, Inc.

PCPI is committed to encourage member companies to develop ethical interactions with healthcare professionals, respecting their independence, and designed to benefit patients and uplift the practice of medicine.

IV. CODE OF BUSINESS ETHICS

1. Interactions with Healthcare Professionals

- A. Member companies provide healthcare professionals valuable information about pharmaceutical products that lead to improved patient care.
- B. Using appropriate marketing tools, the information Companies provide helps ensure that pharmaceutical products are used correctly for maximum patient benefit. Companies value relationships established with healthcare professionals because these relationships:



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Philippine Chamber of the Pharmaceutical Industry, Inc.

- 1) inform healthcare professionals about the benefits and risks of medicines to help advance appropriate patient use;
 - 2) provide scientific and educational information;
 - 3) support medical research and education; and
 - 4) obtain feedback and advice about the products through consultation with medical experts.
- C. These interactions, that form the backbone of relationships with healthcare professionals, are conducted in a professional and ethical manner.
- 1) Company relationships with healthcare professionals are regulated by multiple entities and intended to benefit patients and to enhance the practice of medicine. Interactions are primarily focused on informing healthcare professionals about products, providing scientific and educational information, and supporting medical education.
 - 2) The education and promotional activities that companies conduct encourage the appropriate



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Philippine Chamber of the Pharmaceutical Industry, Inc.

use of pharmaceutical products by presenting them objectively and without exaggerating their properties and benefits.

- 3) These relationships encourage the development of a medical practice committed to patients' well-being and based on truthful, accurate, and updated scientific evidence.
- 4) Companies do not use these relationships to interfere with the independence of a healthcare professional's prescribing or dispensing practices. Companies do not oblige or induce prescribing or dispensing, or recommending of healthcare professionals.

2. Promotional Information and Activities

- A. Member companies promote for use and for sale only those pharmaceutical products approved by the Philippine Food and Drug Administration (FDA)



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Philippine Chamber of the Pharmaceutical Industry, Inc.

for marketing, through the issuance of the Certificate of Product Registration (CPR).

- 1) The promotion of the pharmaceutical product is consistent with FDA-approved product information as detailed in the CPR.
 - 2) Member companies make available pertinent and appropriate information about the pharmaceutical product to all healthcare professionals, as allowed by applicable laws and regulations, and approved by the FDA.
- B. The promotional information is clear, legible, accurate, balanced, fair, objective and sufficiently complete to enable healthcare professionals to form his or her own opinion of the therapeutic value of the pharmaceutical product concerned.
- 1) Promotional information is factual, based on an up-to-date evaluation of all relevant evidence and reflects that evidence clearly. It does not mislead by distortion, exaggeration, undue emphasis, omission or in any other way.



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Philippine Chamber of the Pharmaceutical Industry, Inc.

- 2) Promotional information is capable of substantiation either by reference to the FDA-approved labeling or by scientific evidence. Such evidence is made available on request to healthcare professionals. Companies deal objectively with requests for information made in good faith and provide data that are appropriate to the source of the inquiry.
- 3) Promotion information provided is in compliance with applicable laws and regulations, and local, national, and industry code of ethics.
- 4) Materials sponsored by a Company relating to medicines and their uses, whether promotional in nature or not, clearly indicate by whom they have been sponsored.



3. Safety of Medicines

- A. Pharmaceutical products provided by member companies conform to high standards of quality, safety and efficacy as determined by the FDA.
- B. Member companies report adverse events or adverse drug reactions to the FDA as part of their pharmacovigilance responsibility, in compliance with the code of the FDA.

4. Symposia and Congresses

- A. Companies organize or sponsor "events" (symposia, congresses and other promotional or non-promotional, scientific or professional meetings) for healthcare professionals primarily to inform healthcare professionals about products and/or to provide scientific or educational information. Companies are encouraged to partner



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Philippine Chamber of the Pharmaceutical Industry, Inc.

with professional medical organizations and societies in the sponsorship of such events.

- B. Any sponsorship provided to individual healthcare professionals is not conditional upon an obligation to prescribe, recommend, or promote any medicine.
- C. These events are held in an appropriate venue that is conducive to the scientific or educational objectives and the purpose of the event. Companies refrain from using extravagant venues or resorts that may distract participants from the purpose of the event.
- D. Companies provide hospitality to participants like refreshments and/or meals incidental to the main purpose of the Event. The hospitality is limited to participants of the event and not their guests. The cost of the hospitality is perceived as prudent, moderate and reasonable and not lavish, excessive and extravagant.



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Philippine Chamber of the Pharmaceutical Industry, Inc.

- E. Companies refrain from shouldering the costs associated with individuals accompanying invited healthcare professionals.

5. Information Presentations by Company Representatives

- A. Company representatives provide scientific and educational information to healthcare professionals through presentations. These presentations may be made during healthcare professionals' working day, including meal times, respecting the professionals' working schedules and provision of patient care.
 - 1) During presentations where occasional meals are provided as a necessity to the healthcare professionals, and may include members of their staff in attendance, the cost of such meals is perceived as prudent, moderate and reasonable and not lavish, excessive and extravagant.



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Philippine Chamber of the Pharmaceutical Industry, Inc.

- 2) These presentations are primarily informational and educational in purpose and not for entertainment or recreation. Hence, these presentations are made in a manner conducive to this purpose.
- 3) These presentations usually will not include invited healthcare professional's guests (including spouses) who will not benefit from the presentation. The meals provided are consumed during the presentation. Company representatives refrain from offering these meals for consumption outside of the presentation.

6. Entertainment

- A. Company interactions are professional in nature and facilitate the exchange of medical or scientific information that will benefit patient care.



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Philippine Chamber of the Pharmaceutical Industry, Inc.

- 1) Companies do not provide forms of recreation and entertainment to healthcare professionals with the purpose of obliging or inducing them to prescribe, dispense the companies' pharmaceutical products.
- 2) The cost of such forms of recreation and entertainment is perceived as prudent, moderate and reasonable and not lavish, excessive and extravagant.
- 3) At events sponsored or organized by Companies, entertainment of prudent, moderate and reasonable in nature, which is secondary to refreshments or meals, may be provided.



7. Educational Items and Gifts

- A. Companies do not provide nor offer healthcare professionals cash or cash equivalents (such as gift certificates) or gifts for their personal benefit.
- 1) Companies may offer and provide items to healthcare professionals designed primarily for providing information to healthcare professionals or for the education of patients. The cost of these items are perceived as prudent, moderate and reasonable and not lavish, excessive and extravagant. And these are usually of value to the practice of their profession.
 - 2) Companies provide these items not to subsidize routine operations of practice of the healthcare professional.



8. Support for Continuing Professional Education

- A. Continuing professional education "CPE" (e.g. continuing medical, pharmacist education) helps healthcare professionals to obtain information and gain insights that can contribute to the improvement of patient care and the medical practice.

Companies have objective criteria for making CPE grant decisions to ensure that programs funded are bona fide and quality educational programs. The financial support provided is not an inducement to prescribe, dispense or recommend a particular pharmaceutical product or course of treatment.

- B. Companies provide or offer grants, scholarships, subsidies, support, consulting contracts, educational or practice-related items for the purpose of supporting legitimate education, scientific, or medical research. These are not meant to interfere with the ethics and the



independence of a healthcare professional's prescribing, dispensing practices.

9. Samples

- A. In certain pharmaceutical products or product categories, samples are important tools for healthcare professionals and provide direct benefit to patient health outcomes.
- B. Companies provide samples of pharmaceutical products free of charge to healthcare professionals in order to enhance patient care. Healthcare professionals do not resell or misuse samples.
 - 1) Companies have adequate systems of control and accountability for samples provided to healthcare professionals including how to look after such samples while they are in possession of medical representatives.



- 2) Companies provide samples not to be used as payment for services, return for favorable treatment, or other inappropriate inducements.

10. Consultant and Speaker Arrangements

- A. Consulting arrangements with healthcare professionals allow companies to obtain information or advice from experts on such topics as the marketplace, products, therapeutic areas and the needs of patients. Companies use this advice as basis for their efforts to ensure that the pharmaceutical products they develop, produce and/or market are meeting the needs of patients. In addition, healthcare professionals participate in Company sponsored speaking programs in order to help educate and inform other healthcare professionals about the benefits, risks, and appropriate uses of medicines.
 - 1) Companies are aware that such consultant and speaking arrangements are neither



inducements nor rewards for prescribing, dispensing or recommending a particular pharmaceutical product or course of treatment.

- 2) Companies offer and provide reasonable compensation for such consultant and speaking arrangements to include reimbursement for travel, lodging, and meal expenses incurred as part of providing those services. The cost of compensation of this consulting or speaking arrangement is based on fair market value, and perceived as prudent, moderate and reasonable and not lavish, excessive and extravagant.
- 3) These consultant and speaking arrangements will not include invited healthcare professional's guests (including spouses and family members). The meals provided are consumed during the presentation. Company representatives refrain from offering these meals for consumption outside of the presentation.



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Philippine Chamber of the Pharmaceutical Industry, Inc.

- 4) Companies do not use such consulting and speaking arrangements as a means to compensate healthcare professionals without a bona fide business purpose.
- B. Companies provide consulting and speaking arrangements that are best supported by one or more of the following:
- 1) a written contract specifies the nature of the services to be provided and the basis for payment of those services;
 - 2) a legitimate need for the services identified in advance of requesting the services and entering into arrangements with the prospective consultants;
 - 3) criteria for selecting consultants and speakers that are related to the identified purpose, and the persons responsible for selecting the consultants and speakers have the expertise necessary to evaluate whether the particular healthcare professionals meet those criteria;



- 4) Company-maintained records concerning the services provided;

11. Conduct and Training of Company Representatives

- A. Company representatives play an important role in delivering accurate, up-to-date information to healthcare professionals about the approved indications, benefits and risks of pharmaceutical products. These representatives often serve as the primary point of contact between the Companies and the healthcare professionals. As such, Company representatives act with the highest degree of professionalism and integrity.
 - 1) Company representatives, employed by or acting on behalf of the companies, who visit healthcare professionals have received adequate and regular training on general science and product-specific information, and on the applicable laws and regulations and the codes of ethics that govern their interactions



with healthcare professionals. The training guarantees that the information they provide accurate, up-to-date information.

- 2) Companies periodically assess their representatives to ensure that their knowledge is accurate, relevant and current and that they comply with relevant Company policies and standards of conduct.
- 3) Companies take appropriate action when representatives fail to comply with relevant Company policies particularly those consistent with industry codes of ethics.

12. Public Sector Relationships and Procurement

- A. Companies interact with the government in a professional and ethical manner. The companies do not attempt to exert inappropriate influence on government processes, particularly in procurement and bidding.



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Philippine Chamber of the Pharmaceutical Industry, Inc.

- B. Companies provide accurate and balanced information to the Government.
- C. Companies' relationships with government representatives and official, including fee-for service arrangements, comply with government ethics rules or procedures.

13. Company Donations for Charitable Purposes

- A. As a demonstration of good corporate citizenship, Companies recognize their responsibility to support worthwhile activities both within and outside our communities.
 - 1) Pharmaceutical products donated for medical missions are not less than 4 months in remaining shelf life. Ethical pharmaceutical products are endorsed by the company medical director for donation.
 - 2) Donations including donations in kind, may be provided to organizations and institutions



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Philippine Chamber of the Pharmaceutical Industry, Inc.

involved in promoting activities such as artistic, charitable, cultural, community, educational, humanitarian, health, philanthropic, and sporting activities in accordance with applicable laws and regulations.

- 3) Companies provide such support not for product promotional reasons.
- 4) Companies direct such support, funding and donations in-kind, to organizations and document these in a manner that outlines the nature of the donation provided.

B. Companies provide such support with no intention to oblige or induce prescribing, dispensing or recommending the purchase, supply or administration of a specific product. Companies do not offer such support to interfere with the independence of a healthcare professional's prescribing or dispensing practices.



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Philippine Chamber of the Pharmaceutical Industry, Inc.

14. Clinical Trials

- A. All clinical trials (phases I to IV) and scientific research involving patients sponsored or supported by companies will be conducted with the intent to develop bona fide scientific knowledge that will benefit patients and advance science and medicine. Companies must ensure transparency and accountability in the presentation of research and publication of study results.
- B. Clinical trials should not be used as inappropriate inducements for past or future sales.
- C. Clinical trials should be undertaken in an ethical manner, without undue influence by competitors.



15. Patient Organizations

- A. Companies respect the autonomy and independence of patient organizations.
- B. Companies offer or provide support to patient organizations that are not conditional on the promotion of specific product/s or course of treatment.

16. Adherence to the Code

- A. Companies interact with healthcare professionals, government officials, and other stakeholders adopt policies and procedures to assure adherence to the Code and local, national, and regional industry codes of ethics.
- B. These policies and procedures are properly documented and provided to employees. The Companies conduct training on these policies and procedures to further enhance adherence.



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Philippine Chamber of the Pharmaceutical Industry, Inc.

- C. Healthcare professionals, public sector officials and representatives, and other stakeholders are aware of the Code, respect its implementation and adopt standards consistent with the Code, if applicable.