



PHARMACEUTICAL & HEALTHCARE
ASSOCIATION OF THE PHILIPPINES



Foreword

The PHAP Code of Practice adopts in full and aligns with the Department of Health Administrative Order No. 2015-0053 Implementing Guidelines on the Promotion and Marketing of Prescription Pharmaceutical Products and Medical Devices, Expanded Code of Practice of the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) and the Mexico City Principles for Voluntary Codes of Business Ethics in the Biopharmaceutical Sector. It incorporates local requirements and practices in relation to registration; labeling and scientific claims approved by the Philippine Food and Drug Administration (FDA).

PHAP and its members are committed to educational and promotional efforts that benefit patients as well as programs and collaborations that enhance the practice of medicine. PHAP through its Code of Practice seeks to preserve the independence of the decisions taken by healthcare professionals (HCPs) in prescribing medicines to patients.

The ethical promotion of prescription medicines is vital to the pharmaceutical industry's mission of helping patients through research and development of new and innovative medicines. Ethical promotion helps to ensure that HCPs have access to the right information they need and that right patients have access to the right medicines at the right time.

Industry relationships with HCPs must support, and be consistent with the professional responsibilities they have with their patients. Pharmaceutical companies must maintain high ethical standards in the conduct of promotional activities to HCPs, Patient groups and Patient Organizations and comply with applicable legal, regulatory and professional requirements.

Through the promotion of this Code, PHAP seeks to ensure that ethical promotional practices are established and be at par with International Standards worldwide.



TEODORO PADILLA

Executive Director

Member's Pledge

As a PHAP Member, I acknowledge our company's responsibility to adhere to the Code of Practice in our commitment to operate our businesses ethically and with integrity.

I pledge to uphold the Guiding Principles of the Code of Practice such as integrity, transparency, independence, accountability and patient focus to ensure that all our interactions with public and private sectors, healthcare professionals, medical institutions and patient organizations, are at all times ethical, appropriate and professional.

As Delegate, I recognize my role in leading the promotion of the Code of Practice among company employees through information and education and thorough training.

Company

Print Name of Delegate
Signature

Date

MEMBER'S PLEDGE

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Company

Print Name of Delegate
Signature

Date

(Please send this portion of the signed Member's Pledge to PHAP)

September 20, 2016 version

PHAP Board of Trustees

The PHAP Board of Trustees (BOT) sets the policies for the PHAP Code of Practice. It has the responsibility of ensuring that all member companies abide by the code.

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Mr. Teodoro Padilla
Executive Director
PHAP

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Ethics Committee

While the Board of Trustees sets policies and rules, it appoints an independent body composed of experts from the academe, business ethics, and the healthcare sector to adjudicate complaints relating to breaches of the PHAP Code of Practice.

In the context of transparency, rulings issued by the PHAP Ethics Committee (EC) will be posted in the PHAP website.

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PHAP

Teodoro B. Padilla
Executive Director
Liaison to PHAP Board

September 20, 2016 version

Appeals Board

Appeals Board

In the instance that either the complainant or the accused contests the ruling of the EC, the issue may then be elevated to the Appeals Board (AB). Decisions by the AB are final and executory.

The composition of the AB shall be drawn from an independent pool of experts.

September 20, 2016 version

User's Guide

The Code Of Practice enumerates the rules implementing the eight (8) guiding principles with explanatory notes as guides whenever necessary. This version incorporates all released circulars and the latest amendments and modifications and therefore supersedes all prior rules.

For ease and convenience, the Code is rendered in a ring binder format. Amended sections shall be replaced with the new guidelines and the old ones transferred to the latter portion of the Code Book. This shall serve as a reference for tracking the Code Of Practice amendment history.

An expanded "index" portion containing keywords/ phrases that enable easier and faster access to specific provisions of the Code is provided.

September 20, 2016 version



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PHARMACEUTICAL & HEALTHCARE
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Code of Practice

PHAP Code	Explanatory Notes
<p data-bbox="189 157 508 204" style="text-align: center;">PHAP Guiding Principles On Ethical Conduct and Promotions</p> <p data-bbox="130 236 567 361">The following Guiding Principles set out basic standards that apply to the conduct of PHAP Member Companies and their agents. This helps ensure that their interactions with stakeholders are appropriate.</p> <ul style="list-style-type: none"> <li data-bbox="179 364 567 461">• The healthcare and well being of patients are the first priority for pharmaceutical products and medical devices companies. <li data-bbox="179 465 567 562">• Pharmaceutical and medical devices companies will conform to high standards of quality, safety and efficacy as determined by regulatory authorities. <li data-bbox="179 565 567 795">• Pharmaceutical and medical devices companies' interactions with stakeholders must at all times be ethical, appropriate and professional. Nothing should be offered or provided by a company in a manner or on conditions that would have an inappropriate influence to ensure the independence of the Healthcare Professional (HCP). <li data-bbox="179 798 567 895">• Pharmaceutical and medical devices companies are responsible for providing accurate, balanced, and scientifically valid data on products. <li data-bbox="179 899 567 1048">• Promotion must be ethical, accurate, balanced and must not be misleading. Information in promotional materials must support proper assessment of the risks and benefits of the product and its appropriate use. <li data-bbox="179 1052 567 1124">• Pharmaceutical and medical devices companies will respect the privacy and personal information of patients. <li data-bbox="179 1128 567 1277">• All clinical trials and scientific research sponsored or supported by companies will be conducted with the intent to develop knowledge that will benefit patients and advance science and medicine. 	

<ul style="list-style-type: none"> • Pharmaceutical and medical devices companies are committed to the transparency of industry sponsored clinical trials in patients. • PHAP Member Companies should adhere to both the spirit and the letter of this Code and ensure that all relevant personnel are appropriately trained. The PHAP Code of Practice covers not only member companies but also local subsidiaries of IFPMA member companies. 	
<p>1.0 Code of Pharmaceutical Marketing Practices</p> <p>1.1 Scope of Coverage</p> <p>The promotion and advertisement of pharmaceutical products and medical devices directed to HCPs are deemed to fall within the scope of the Code.</p> <p>1.2 Public Sector Relationships and Procurement</p> <p>The decision-making process by Companies and Governments during and including the government procurement process, through bidding or any other procedure of government procurement, must be professional and ethical. There should be no attempt to exert inappropriate influence.</p> <p>Companies must provide accurate and balanced information to the Government.</p> <p>Companies and government officials should ensure that their relationships and fee-for-service arrangements comply with government ethics rules or procedures.</p> <p>Adherence to Principles</p> <p>All Companies that interact with healthcare professionals, government officials, and other stakeholders should adopt procedures to assure adherence to these principles and local, national, and regional industry codes of ethics. Healthcare professionals, government officials, and other stakeholders should respect these principles and adopt consistent standards if applicable.</p>	<p>1.1 The Code also covers promotion and advertisement of over the counter medicines and medical devices to healthcare professionals.</p>

1.3 Definition of terms

PPMD - Prescription Pharmaceutical Products and Medical Devices

Agents and Third Party Agents are external sales force such as CROs, CSOs, Promotion, Co-promotion agreements.

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.

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.

Events mean 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.

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

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.

Medical Representatives/ Professional Service Representatives (PSR) means company representatives whose regular duties comprise or include interaction with or conducting business calls to healthcare professionals to provide them with information and/or any other purpose concerning the company's products/ services.

Pharmaceutical product means any pharmaceutical or biological product (irrespective of patent status and/or whether the product is branded or not) which is intended to be used on the prescription of, or under the supervision of, an HCP, and which is intended for use in the prevention, diagnosis and treatment of disease in humans, or to affect the structure or any function of the human body.

Promotion and advertisement means any activity undertaken, organized or sponsored by a member company, which is directed at HCPs to promote the prescription, recommendation, supply, administration or consumption of its pharmaceutical product(s) through any medium, including the internet.

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

<p>Patient Organization means any formally organized and reputable not-for-profit institution that primarily represents the interests and needs of patients, their families and/ or caregivers.</p> <p>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.</p>	
<p>1.4 Interpretation of the Code</p> <p>In case of doubt, the interpretation consistent with the 8 guiding principles shall be adopted. In case of conflicting rules or provisions (within the PHAP Code or involving other laws and government regulations), the more stringent rule or provision shall apply.</p> <p>1.5 Responsibility for Implementation</p> <p>The General Manager/President/Managing Director is responsible for the proper implementation of the Code and its implementing guidelines within his/ her company.</p> <p>1.6 Agents and Third Party Partners “Organization” shall extend to agents, third party partners interacting with healthcare professionals on behalf of the member company.</p> <p>1.7 Exclusions of the Code</p> <p>This Code does not seek to regulate the following activities:</p> <ul style="list-style-type: none"> • Promotion / advertising of over – the-counter medicines to the general public. • Pricing or other trade terms for the supply of pharmaceutical products and medical device. 	

<p>2.0 Medical Information and Promotional Claims</p> <p>All promotional content (in printed/ electronic form, or communicated orally) must be accurate, scientifically sound and objective, reflect the current state of knowledge and must be consistent with the FDA approved labeling.</p> <p>All promotional claims must be substantiated and referenced (indicated by a footnote or endnote on the same material that the claim is made).</p> <p>Data on file may be used as reference and made available upon request.</p> <p>You can use the word “new” in your detail materials only when it has been made available to the market for not more than 12 months.</p> <p>2.1 Accurate and Not Misleading (IFPMA p. 5)</p> <p>Promotional information should be clear, legible, accurate, balanced, fair, and sufficiently complete to enable the recipient to form his or her own opinion of the therapeutic value of the pharmaceutical product concerned. Promotional information should be based on an up-to-date evaluation of all relevant evidence and reflect that evidence clearly. It should not mislead by distortion, exaggeration, and undue emphasis, omission or in any other way. Every effort should be made to avoid ambiguity. Absolute or all- embracing claims should be used with caution and only with adequate qualification and substantiation. Descriptions such as “safe” and “no side effects” should generally be avoided and should always be adequately qualified.</p> <p>Unqualified superlatives must not be used.</p> <p>Comparison of products must be factual, fair and capable of substantiation and referenced to its source.</p>	<p>Pharmaceutical advertising commonly contains comparisons with other products, and such comparisons are usually made to show the advantages of the advertised product over those of its competitor(s).</p> <p>Provided that such comparisons with other products are factual, fair and can be substantiated, they are acceptable under the Code.</p> <p>The intention of this clause is to prohibit unfair and unjustified comparisons with the products or activities of competitors.</p> <p>Where a claim of comparative efficacy or safety is made, it must not be based solely on a comparison of Product Information documents that do not reflect the general literature, as those documents are based on different databases and are not directly comparable. This applies to Philippine as well as overseas Product Information documents.</p> <p>Claims of comparative efficacy or safety should be based on data from adequate and well-controlled clinical trials, and if they are consistent with the body of other clinical data.</p> <p>The accepted level of statistical significance is $P < 0.05$. If comparative data that are not statistically significant are used, such data must comply with the following conditions:</p> <p>Lack of significance must be stated explicitly; it is insufficient to state the p value; and</p> <p>The data must not be used to generalize or to indicate superiority or inferiority.</p>
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2.2 Pre-Approval Communications and Off-Label Use

No pharmaceutical product shall be promoted for use until the requisite approval for marketing for such use has been given.

This provision is not intended to prevent the right of the scientific community and the public to be fully informed concerning scientific and medical progress. It is not intended to restrict a full and proper exchange of scientific information concerning a pharmaceutical product, including appropriate dissemination of investigational findings in scientific or lay communications media and at scientific conferences. Nor should it restrict public disclosure of information to stockholders and others concerning any pharmaceutical product, as may be required or desirable under law, rule or regulation.

(IFPMA p. 5)

2.3 Substantiation

Promotional claims should be capable of substantiation either by reference to the approved labeling or by scientific evidence. Such evidence should be made available on request to healthcare professionals. Companies should deal objectively with requests for information made in good faith and should provide data, which are appropriate to the source of the inquiry. Any information or quotation derived from publications must mention the complete source (at least in a footnote), i.e., name of the author, title of the publication, name of the journal, volume and page number, and year of publication. **(IFPMA p. 5)**

2.4 New Products

The word "new" can be used only to refer to product presentation, or therapeutic indication that has been available and generally promoted for not more than 12 months.

The statement that the claim is not statistically significant needs to be linked in some manner to the original claim, made on the same page and within a reasonable proximity to the original claim in a manner that is not obscured by other material, and using a type size of not less than 2mm. Care should be taken to distinguish between mathematically determined statistical significance on one hand and clinical significance on the other hand.

<p>2.5 Medical Ethics</p> <p>No Prescription Pharmaceutical Products and Medical Device 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. (DOH AO 2015-0053 Sec 2 Letter E)</p>	
<p>3.0 Product Information</p> <p>The PHAP is committed to the rational use of medicines, and central to this goal is the provision of relevant information to Healthcare Professionals. Such information should include knowledge gained from the research and development of medicines as well as from their clinical use. HCPs in the Philippines should have access to similar data as those being communicated in developed countries.</p>	
<p>4.0 Content of Promotional Materials</p> <p>4.1 Promotional content shall be consistent with the indications in the Certificate of Product Registration (CPR) and labeling materials as approved by the FDA. (DOH AO 2015-0053)</p> <p>4.2 General requirements of promotional material:</p> <ol style="list-style-type: none"> 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 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. 	

4.3 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 No. 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

4.4 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.

4.5. 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 test 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

4.6. 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.

4.7. 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.

4.8. Claims

a. All claims shall be accurate and substantiated from legitimate sources and be made available upon request.

b. The use of phrases such as “Drug of first choice” or “The number 1 drug” shall be supported by up to date, sufficient and appropriate clinical evidence.

c. Requirements for Comparative Claims:

c.1 Claims properly supported by scientific data and in accordance with local regulations may be allowed;

c.2. The use of adverse drug reaction data to compare two (2) drug products in promotional materials may be allowed to demonstrate a full, fair, and balanced comparison;

c.3. Superiority claims may be allowed if supported by competent (measuring up to all requirements) and well-controlled clinical trials; and

c.4 Claims related to difference in efficacy between drugs may be allowed if it is clinically relevant and statistically significant ($p < 0.05$).

Pursuant to Section 2 of DOH AO 2015-0053:

4.9 Promotional Information and Activities

a. Information provided by (PPPM) 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 PPPMs, 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 Prescription Pharmaceutical Products and Medical Device 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 (DOH AO 2015-0053, Sec 2, A to D)

4.9.1 Educational Items

Prescription Pharmaceutical Products and Medical Device companies may occasionally provide items of medical utility to Healthcare Organizations (HCOs) such as textbooks,

<p>subscriptions to medical journals or anatomical models, which benefit patients or serve a genuine educational function for the HCO. Items of medical utility should be modest. (DOH AO 2015-0053, Sec 7, D.)</p>	
<p>5.0 Other Communication Channels</p> <p>5.1 These channels include all non-face-to-face interactions like social media, email, fax and SMS (Text messages).</p> <p>These forms of communications must comply with all relevant provisions of the Code.</p> <p>5.2 These communications should be sent only to those categories of healthcard professionals whose need for, or interest in, the particular information can be reasonably assumed. Requests to be removed from promotional mailing lists must be complied with promptly, and no name should be restored except upon specific request or with written permission.</p> <p>5.3. Mailing lists should be kept up-to-date.</p> <p>5.4 Exposed mail, including postcards, envelopes, and wrappers must not carry matter that might be regarded as advertising to the general public or that could be considered unsuitable for public view.</p>	
<p>6.0 Medical Representatives/ Professional Service Representatives (PSR)</p> <p>6.1 Medical representatives/ Professional Service Representatives should possess sufficient medical and technical knowledge to present information on the company's products in an accurate, current, and balanced manner, and should be cognizant of all provisions of this Code.</p> <p>6.2 Members have a responsibility to maintain high standards of continuing competency training for representatives and shall be required to conduct the mandatory courses under the Integrity and Proficiency Program in the Pharmaceutical Sector (IPPS) or its equivalent.</p>	<p>6.0 Medical Representatives/ Professional Service Representatives (PSR)</p> <p>Company representatives whose regular duties comprise or include interacting with or conducting business calls to healthcare professionals to provide them with information and/or any other purpose concerning the company's products/services.</p>

6.3 Medical representatives/ Professional Service Representatives should, at all times, maintain a high standard of ethical conduct in discharging their duties.

6.4 Medical Representatives/Professional Service Representatives should complete the training and pass the assessment under the IPPS.

6.5 Medical representatives/Professional Service Representatives must ensure that calls do not inconvenience or hinder the HCPs' performance of their duties. Medical representatives should conform to institutional regulations governing their calls.

6.6 Conduct of Training of Prescription Pharmaceutical Products and Medical Device 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.

<p>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. (DOH AO 2015-0053 Sec 12)</p>	
<p>7.0 Product Samples</p> <p>7.1 In accordance with FDA regulations, free samples of a pharmaceutical product may be supplied to healthcare professionals, and only with their consent, in order to enhance patient care or to gain clinical experience. Samples should not be sold or otherwise misused by medical representatives and employees.</p> <p>7.2 The quantity of samples given should be appropriate for HCPs to:</p> <p>7.2.1 Initiate therapy; and/or</p> <p>7.2.2 Gain clinical experience with the product.</p> <p>7.3 Product samples may be given for humanitarian reasons, but dispensing must be under the supervision of a qualified HCP</p> <p>7.4 Product samples must be accompanied by product inserts</p> <p>7.5 Product samples must comply with the labeling requirements of FDA, and must be clearly marked "Physician's Sample - Not For Sale."</p> <p>7.6 Companies should have adequate systems of control and accountability for samples provided to healthcare professionals including how to look after such samples whilst they are in possession of medical representatives. (8.2 of IFPMA)</p>	

<p>7.7 Samples should not be used as payment for services, return for favorable treatment, or other inappropriate inducements. (MCP, p. 8)</p> <p>7.8 Samples are duly acknowledged by the HCP and HCO (DOH AO2015-0053 Sec 9, Letter A)</p>	
<p>8.0 Events And Meetings</p> <p>8.1 General Guidelines</p> <p>8.1.1 Scientific and Educational Objectives</p> <p>The purpose and focus of all symposia, congresses and other promotional, scientific or professional meetings (an “Event”) for healthcare professionals organized or sponsored by a company should be to provide scientific or educational information and/or inform healthcare professionals about products.</p> <p>8.1.2 Sponsorship</p> <p>Sponsorship of the HCP must be limited to travel to and from the venue (and meals and accommodations) for the duration of the Event with possibility of extending one (1) day before and one (1) day after the Event if warranted by logistical considerations (e.g., flight schedule). Sponsorship of entertainment or side trips of the HCP within or outside of the duration of the Event is not allowed.</p> <p>8.2. Appropriate Venue</p> <p>All Events must be held in an appropriate venue that is conducive to the scientific or educational objectives and the purpose of the Event or meeting.</p> <p>Hotels and establishments which are located at beachfronts and considered as beach resorts as well as those that primarily offer spa, sports, entertainment, leisure or other recreational facilities, as well as those that operate casino/ casino facilities, and/or golf courses within their premises are considered inappropriate venues.</p>	<p>“Recreational” for the purposes of this Code is understood to mean that the establishment primarily offers or markets itself as a venue for sports and/or leisure, such as country clubs, golf clubs, sports clubs or sports complex, resorts complex, entertainment complex and the like.</p> <p>For example, since John Hay is considered a leisure area, the PHAP Board of Trustees Decision dated 13 March 2015 is upheld such that “For CME events that are to be held in Baguio xxx, the Baguio Convention Center and the CAP Convention Center are considered acceptable as venues for holding such activities.”</p>

Likewise, hotels and establishments that are either located within, which means attached or connected to, or are part of a recreational, entertainment or leisure area such as country clubs, golf clubs, sports clubs as well as resorts or sports, entertainment or leisure complexes are not allowed as venues for scientific meetings. In case of change of classification of appropriateness of a venue, PHAP should give at least six months prior notice to its members. The members will be strongly advised on alternative solutions to the extent possible under the circumstances and likewise taking into consideration the time constraints.

The geographical location is in or near a city or town, which is a recognized scientific or business center and is easily accessible for the intended audience. The location and venue should not be the main attraction of the event or to be perceived as such. The time of the event should not conclude with local or internationally recognized sporting or cultural events taking place in the same location, at the same time and preferably not just before or just after the meeting.

The location is appropriate in respect to the geographical scope of the event.

8.3 Events

1. Symposium and Congress

General Guidelines:

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 Code;

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.

A. Company Organized

B. Third Party

B.1 HCP/Medical Societies - Member companies should not specifically support:

- Sports events, such as fun runs, golf tournaments, etc.

- Fund-raising activities, such as movie premieres, dinners, chorales, concerts, etc.

- Fellowship nights during congresses, conventions and the like.

B.2 Patient Organizations - Companies may provide financial support for patient organization meetings provided that the primary purpose of the meeting is professional, educational, and scientific in nature, or otherwise supports the mission of the patient organization. When companies hold meetings for patient organizations, companies must ensure that the venue and location is appropriate and conducive to informational communication. In addition, any meals or refreshments provided by a company must be modest as judged by local standards.

<p>B.3. Hospitals - 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 the DOH AO 2015-0053 or for placards or posters concerning such products except during scientific conventions when their facility is used as its venue. (Adopted from DOH AO 2015-0053)</p> <p>B.4. Pharmacists/Pharmacy clerks in their capacity as HCPs.</p>	
<p>8.4 Exhibit Booths Exhibit booths must be directed only to HCPs. The display must clearly identify the exhibitor and must comply with all the requirements of the organizer and the relevant provisions of this Code.</p> <p>8.4.1 Raffle activities will not be allowed</p> <p>8.4.2 Educational activities may be conducted in booths provided the tokens are limited to promotional aids as defined in DOH AO 2015-0053.</p>	
<p>8.5 Support for Continuing Professional Development (CPD)</p> <p>General Guidelines:</p> <p>The purpose of any continuing professional development activity shall be to provide additional and updated information to HCPs that can contribute to the improvement of patient care. PPPMD companies shall develop objective criteria for making CPD grants to ensure that programs funded are bona fide and quality educational programs. The financial support provided shall not be an inducement to prescribe to recommend a particular pharmaceutical product or medical device or any course treatment.</p> <p>a. Industry sponsorship of HCPs to events involving foreign/local travel shall be allowed but subject to the following conditions:</p>	

<p>1. The purpose of the event is to provide scientific or educational information;</p> <p>2. The travel is justified because:</p> <p>(a) the events 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/cou try; or</p> <p>(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.</p> <p>3. The venue for such event is appropriate and conducive to the educational or scientific objectives of the conference; and</p> <p>4. The selection of the HCPs should be unrelated to prescribing and sale of the Prescription Pharmaceutical Products and Medical Device company's products.</p> <p>5. The sponsorship for travel of HCPs attending events as legitimate participants shall only be for economy class. This particular restriction on the travel arrangement, however, shall not apply to HCPs who are traveling under a specific and legitimate service agreement with the Prescription Pharmaceutical Products and Medical Device.</p> <p>b. 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 to legitimate overseas scientific educational events, a maximum of seven (7) HCPs (for Europe, Americas and Australia) and twelve (12) HCPs (for ASEAN countries, Hongkong, Taiwan, India, Japan, Korea, China and Middle East.</p>	<p>Adapted DOH AO 2015-0053 Sec 8, Letters A, C, D, E</p> <p>Subject to clarification with FDA. In the event that FDA will issue clarification on the rates pertaining to UNDP and Daily Subsistence Allowance, PHAP will issue a Memorandum Circular to the members.</p> <p>For overseas venues, PPPMD companies may sponsor seven (7) HCPs for the Americas, Europe, and Australia .</p> <p>For regional or ASEAN countries, Hong Kong, Taiwan, India, China, Japan Korea and Middle East, companies may sponsor up to twelve (12) HCPs.</p> <p>Adopt the more stringent interpretation. This section will apply to both third party-organized or company-organized events.</p>
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<p>The sponsorship to these events must consider equitable distribution of training opportunities to HCPs. Family members or guests of the HCPs are not allowed to be sponsored.</p> <p>c. 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.</p> <p>d. A PPPMD company, however, may sponsor a Healthcare Professional as 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 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.</p>	
<p>8.6 A pharmaceutical company is allowed to sponsor only HCPs' accommodations, meals, transportation and registration fees for participating in programs of scientific meetings for recognized medical societies (CME meetings), except for local meetings where HCPs should shoulder registration fees to encourage attendance. Cash assistance or check vouchers are not acceptable under any circumstances. Neither is payment of expenses for accompanying guests.</p> <p>8.7 International and Regional Conventions Held in the Philippines</p> <p>In order to allow more local delegates to participate in international and regional conventions, all international or regional CMEs conducted in the Philippines shall be treated as local events, and hence the following provisions shall apply:</p>	

<ul style="list-style-type: none"> • Companies can send more than 12 delegates to the conventions but sponsorship will be limited to meals and accommodations • Delegates must pay for their own registrations fees 	
<p>8.8 Service Provider</p> <ul style="list-style-type: none"> a. Speaker Consultants b. Adboards c. Others <p>General Guidelines:</p> <p>8.8.1 PHAP recommends the amounts in Table 1 as the maximum rates for HCP honoraria for common events conducted within the Philippines. These recommendations are not intended to restrict member companies from providing different rates as long as they are not excessive and they reflect the fair market value of the services provided, taking into consideration such factors as the nature of the services, therapeutic area of expertise, experience level/qualification of the HCP engaged, number of HCPs in the same level of expertise, complexity of the subject matter, duration of the event and the number of event participants.</p> <p>8.8.2 Consultant and Speaker Arrangements</p> <p>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:</p> <ul style="list-style-type: none"> 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; 	<p>Table 1 on Rates of Honorarium was increased based on annual inflationary rate. Added a category for moderator, reactor, etc.</p> <p>Travel outside of Metro Manila is considered outbase. If within the province, travel time consisting of 50 kilometers is still considered as outbase.</p>

<p>d. Disclosure of any potential or actual conflict of interest (Annex B) by the consultant or speaker must be made; and</p> <p>e. Information is to be made public, if and when requested for legitimate purposes</p> <p>HCPs who conduct lectures for international event held in the Philippines are entitled to an honoraria based on the prevailing fair market value relative to the same measures used for non-Filipino HCPs in the same event.</p>	
<p>8.9 Informational Presentations by Company Representatives</p> <p>General Guidelines:</p> <p>When presenting product information, PPPMD company representatives must provide scientific information of educational value to the HCP.</p> <ol style="list-style-type: none"> a. Detailing, Product Presentation b. Focus Group Discussion c. Others <p>8.10 Hospitality & Meals</p> <p>Meals with HCPs</p> <p>Member-companies are required to establish cap amounts for hospitality and meals. A robust monitoring and control system must be in place to ensure the implementation and adherence to the said cap.</p> <p>For tactical activities carried out by Medical Representatives, the amount spent should not exceed the cap set in the Code. This amount is subject to periodic review by member companies.</p>	<p>8.9 Tactical activities refer to the day-to-day activities of Medical Representatives, which include:</p> <p>Meetings with HCPs</p> <ul style="list-style-type: none"> • Small group presentations • Focus group discussions • Product group discussions • Other hospital-based activities. <p>What is the meal cap for tactical activities by Medical Representatives?</p> <p>The meal cap is P1500/person, inclusive of gratuity and tax.</p> <p>Hospitality & Meals</p> <p>Can medical representatives exceed the meal cap for tactical activities but only be reimbursed the maximum allowable amount?</p> <p>This may be viewed as a circumvention of the cap imposed by PHAP. Thus, PHAP encourages companies to set up policies and processes that will not allow the use of private funds by employees to engage in activities that are not allowed under the Code.</p>

<p>8.11 Entertainment and Recreation</p> <p>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.</p> <p>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.</p> <p>c. No stand-alone entertainment or other leisure or social activities shall be provided or paid for by companies during scientific meetings.</p> <p>d. PPPMD companies are prohibited from paying any travel sponsorship, meals, or other expenses of accompanying guests or family. (DOH AO Sec 6)</p>	
<p>9.0 Independence of Healthcare Professionals</p> <p>Member companies' relationships with healthcare professionals and other stakeholders are intended to benefit patients and to enhance the practice of medicine. Interactions should be focused on informing healthcare professionals about medicines, providing scientific and educational information and supporting medical research and education. (Sec. 2.1 of IFPMA Code)</p> <p>No financial benefit or benefit-in-kind (including grants, scholarships, subsidies, support, consulting contracts or educational or practice-related items) may be provided or offered to a healthcare professional in exchange for prescribing,</p>	

<p>recommending, purchasing, supplying or administering products or for a commitment to continue to do so. Nothing may be offered or provided in a manner or on conditions that would inappropriately influence on a healthcare professional's prescribing practices. Gifts of any kind for the personal benefit of healthcare professionals are not allowed, irrespective of value, kind or occasion.</p>	
<p>9.1 Gifts</p> <p>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.</p> <p>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 healthcare professional or members of their families.</p> <p>c. Wreaths given on the occasion of the death of an HCP may be allowed.</p>	<p>9.1 In particular, cash gifts or equivalents are completely not acceptable. Considered cash equivalents are gift certificates, prepaid cell phone loads, gasoline-cards, and the like.</p> <p>Subject to clarification with FDA. In the event that FDA will issue clarification on this matter, PHAP will issue a Memorandum Circular to the members.</p>
<p>10.0 Clinical Studies and Related Activities</p> <p>This section covers the conduct of investigators' meetings and presentations related to clinical trials and sponsored by pharmaceutical companies held locally or outside the country.</p> <p>10.1 Clinical trials are scientific investigations using valid study designs conducted according to protocols or study descriptions approved by the FDA and a duly established independent institutional review board or Ethics Committee.</p> <p>10.2 Any type of clinical study or research program involving humans (pre- and post-authorization, interventional and non-interventional) must be conducted in compliance with the principles of Good Clinical Practice as laid down in the Declaration of Helsinki.</p> <p>10.3 All such studies must address meaningful medical or scientific topics, e.g. the clinical profile of a product such as safety, efficacy, modes of action or performance related to other treatments.</p>	<p>How does one ensure transparency in the conduct of Clinical trials?</p> <p>As stated in FDA Circular (2012-007) which discusses the role of ethical boards on the conduct of Clinical Trials on Investigational research on Medicinal products. The General Objectives section, as well as in item 5 of its Implementing Guidelines mandate the registration of all research activities to a national registry to with:</p> <p>C. Mandatory Inclusion of Clinical Trials in the Philippine Trial Registry. All Clinical Trials are to be uploaded in the Philippine Clinical Trial Registry.</p> <ul style="list-style-type: none"> • It is the responsibility of the Study sponsor to upload information related to the clinical trial it is conducting to the registry (http://registry.healthresearch.ph) 30 days after the application to conduct the clinical trial has been granted.

<p>10.4 The well being, personal integrity and privacy of participants must always be of highest priority. The informed consent document must appropriately convey all relevant aspects of the study to potential subjects.</p> <p>10.5 Studies in humans must not have the promotion of products as their purpose. Its implementation cannot be used as disguised promotions.</p>	<ul style="list-style-type: none"> • Specific provisions in the publication of Clinical trial results are indicated from items 18 to 20, pages 52 - 53 of the PNHRs National Ethical Guidelines for Health Research 2011 <p>Published data derived from clinical trials/ studies may subsequently be translated into tools for marketing or promotional activities.</p>
<p>10.6 The details of conducting and financing studies must be set out in a written contract. Sponsor Company will only pay remuneration to HCPs, which reflect fair market value for study-related activities.</p> <p>10.7 All clinical trials, once approved for implementation by the FDA, shall be uploaded into the Philippine Clinical Trial Registry as required under local regulations.</p> <p>10.8 All study data must be statistically evaluated. Investigators have in principle the right to publish their data consistent with the pre-agreed study protocol. Authors should have access to all relevant data and statistical assessments to support publications.</p> <p>10.9 Sponsorship to clinical trial investigators' meetings and presentations is allowed subject to the following provisions: Section 8.5 A & D, and 8.6.</p> <p>10.9.1 For investigators' meetings or presentations held outside the country, the limits set forth in this code apply prior to the approval of the study protocol or description.</p> <p>Invitations should be extended only to healthcare professionals in relevant therapeutic areas related to the scientific content, research associate and administrative/technical personnel who are involved in the conduct of clinical trials.</p> <p>10.9.2 Once the protocol or study description has been approved, the maximum number of sponsored healthcare professionals will be limited to two per participating investigational site.</p>	

<p>10.9.3 For clinical trials conducted solely in the Philippines, investigators' meetings held outside the country are not allowed. However, the principal investigator from each participating investigational site may be sponsored to attend if the clinical trial results are presented outside the country, and if the number of sponsored investigators does not exceed limits prescribed under Section 8.5, Letter A.</p>	
<p>11.0 Post-Marketing Surveillances</p> <p>The PMS referred to in Section 11.7 is a type of Phase IV study. There are other Phase IV studies that are not necessarily PMS such as interventional studies for new indications or dosage of drugs with existing market authorization or non-interventional studies such as observational studies in real clinic practice settings. Participation of HCPs in such Phase IV clinical studies can be subsumed under the genuine consultancies and services for medical/scientific studies as defined in Section 12.1 and be entitled to reasonable compensation, provided they comply with the criteria set forth in Section 12.1.</p>	<p>Section 11.7 of the February 2015 PHAP Code of Practice provides:</p> <p>Whereas Post-Marketing Surveillance ceases to be an FDA requirement for drug registration, a member company is not barred from conducting such activity in conformity with its risk management strategies. However, HCPs are not to be compensated for participation to such activities.</p> <p><i>These studies must be subject to review and endorsement of the Philippine Health Research Ethics Board (PHREB) -accredited Ethics Review Committee and approved by the FDA.</i></p>
<p>12. Honoraria</p> <p>12.1 HCPs may be engaged as consultants and advisors for services such as speaking at and/or chairing meetings and events, involvement in medical/scientific studies, clinical trials or training services, participation at advisory board meetings, and participation in market research where such participation involves remuneration.</p> <p>The arrangements that cover these genuine consultancies or other services must, to the extent relevant to the particular arrangement, fulfill all the following criteria:</p> <ul style="list-style-type: none"> a. A contract or agreement must be in place that specifies the nature of the services to be provided and the basis for payment of those services. b. A legitimate need for the services must be clearly identified and documented. 	

<p>c. The criteria for selecting consultants must be directly related to the identified need and the consultants must have the expertise necessary to provide the service.</p> <p>d. The number of consultants engaged must not be greater than the number reasonably necessary to achieve the identified need.</p> <p>e. The hiring of the consultant to provide the relevant service must not be an inducement to prescribe, recommend, purchase, supply, and/or administer any medicine.</p> <p>f. The compensation for the services must be reasonable and reflect the fair market value of the services provided. For honorarium paid for services to be rendered locally, member companies should take into consideration certain criteria, including but not limited to :</p> <ul style="list-style-type: none"> • Nature of services (speaker, chair, moderator, etc.) • Therapeutic area of expertise • Experience level/qualification of HCP engaged • Number of HCPs in same level of expertise • Complexity of the subject matter • Duration of event • Number of event participants 	
<p>13.0 Patient Organization, Patients, Patient Support Programs</p> <p>13.1 Definition</p> <p>13.1.1 Patient Organizations</p> <p>Typically a formally organized and reputable not-for-profit institution that primarily represents the interests and needs of patients, their families and/or caregivers</p> <p>13.1.2 Patients</p> <p>Refers to individuals on therapy of a product, or those that are not on therapy but could benefit by such (e.g. vaccines, or those at risk but not yet on therapy)</p>	<p>13.0 How do we determine a formally organized and reputable not-for-profit institution?</p> <p>The engaging company must do due diligence to establish the reputation and constitution of the organization, e.g., check if there is formal structure (e.g., set of officers, regular meetings, etc.), examine the constitutive documents (articles of incorporation, declaration of membership, credo or similar documents.), on organizational objectives, financial statements, etc.</p> <p>Companies may impose as an additional requirement registration with a government agency (e.g., Securities and Exchange Commission) or recognition by another formal group like the Philippine Medical Association.</p>

<p>13.1.3 Patient Support Programs</p> <p>Programs that involve interaction with patients, including patient education, or programs to ensure patient compliance and adherence</p> <p>13. 2 Interactions with Patient Organizations</p> <p>13.2.1 Scope</p> <p>The pharmaceutical industry has many common interests with patient organizations. All interactions with patient organizations must be ethical. The independence of patient organizations must be respected.</p> <p>13.2.2 Declaration of Involvement</p> <p>When working with patient organizations, companies must ensure that the involvement of the company and the nature of that involvement are clear from the outset.</p> <p>No company may require that it be the sole funder of the patient organization or any of its programs.</p> <p>13.2.3 Written Documentation</p> <p>Companies that provide financial support or in-kind contribution to patient organizations must have in place written documentation setting out the nature of support, including the purpose of any activity and its funding.</p> <p>13.2.4 Events for Patient Organizations</p> <p>Companies may provide financial support for patient organization meetings provided that the primary purpose of the meeting is professional, educational, and scientific in nature, or otherwise supports the mission of the patient organization. When companies hold meetings for patient organizations, companies must ensure that the venue and location is appropriate and conducive to informational communication. In addition, any meals or refreshments provided by a company must be modest as judged by local standards.</p>	<p>This section shall apply to cases where OTC products and medical devices are involved except to the extent allowed by law. For example, promotional interactions with patients and patient organizations involving OTC products may be allowed to the extent provided by law.</p>
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13.2.5 Communication to Patients

Communication with patients should aim at supporting better healthcare and not for purposes of promotion.

Careful consideration needs to be made about the appropriateness, language and style of communication. Therapeutic decisions must be made by HCPs only.

13.3 Disease awareness programs

Any disease awareness programs must be accurate, balanced and materials should be written in appropriate language for the public. The purpose of such programs is to enhance public awareness of diseases, to encourage members of the public to seek treatment for their symptoms and thereby save and/or improve the lives of patients while not promoting the use of any specific product.

13.4 Patient Support Programs

Patient Support Programs (“PSPs”) should have clear objectives, and should maintain HCP independence and protect the rights and privacy of the participants. PSPs must not be designed or used to encourage the use of products in a manner that is inconsistent with the approved product labeling (e.g., no targeting of patient populations outside of the approved product label). All PSPs must comply with applicable laws and regulations (including laws relating to data privacy, drug safety reporting, drug advertising laws, etc.).

13.5 Patient Information

All safety data processing and reporting obligations must be fulfilled. Patient or caregiver data must only be collected and used and disclosed in accordance with applicable privacy laws and all notice and other privacy requirements must be met. Companies must be transparent, clear and unambiguous with patients or patient caregivers about the collection of the data and how it will be used.

<p>All required consents must be obtained and only the minimum amount of data needed for the disclosed purposes should be collected and retained for only as long as needed to achieve the disclosed purpose.</p>	
<p>14.0 Communications With The General Public</p> <p>(Refer to Guidelines On Communication Of Prescription Products To The General Public: Appendix 1.)</p> <p>14.1 Inquiries regarding the use of pharmaceutical products may be construed as practice of medicine; hence, appropriately qualified personnel such as the Product Manager or Medical Director must handle this. Request for advice on diagnosis and treatment must always be referred to a healthcare professional.</p> <p>14.2 The current trend is the rapid transfer of information, awareness and education on the health risks of certain diseases, such as coronary heart disease, diabetes, smoking, respiratory diseases, HIV, tuberculosis, gastrointestinal infection, obesity, influenza, cancer, osteoporosis, menopause, stress and depression. Infomercials covering medical and healthcare topics and treatment options are permitted as long as their content is medically sound, does not encourage self-medication, and directs the readers to consult a doctor, and as long as treatment options are balanced with information on contraindications, precautions, warnings and side effects.</p> <p>14.3 General media articles may be initiated by manufacturers to announce the holding of a scientific event.</p> <p>14.4 Any activity directed to the general public that encourages a patient to consult a healthcare professional for a specific illness is allowed as long as no specific brand is mentioned.</p> <p>14.5 For public service announcements on product withdrawals, batch problems, batch mix-ups, and new warnings about a product that may have serious public health implications,</p>	

<p>brand names together with their corresponding generic names may be used.</p> <p>14.6 Patient education should encourage patients to seek further information or explanation from the appropriate healthcare professional.</p> <p>14.7 The educational material should be current, accurate, and balanced, and should not focus on a particular product unless it is to be given after a particular product has been prescribed.</p> <p>14.8 The educational material must contain a statement directing the patient to seek further information from his or her healthcare professional.</p> <p>14.9 Patient Aids</p> <p>Once a decision to prescribe a product has been made, patient aids that are solely intended to provide information for the patient may be product-specific. The content of such material must be designed to assist patient compliance by providing information that clarifies the method of the administration, precautions and special instructions. Patient aid must not make comparisons or include promotional claims. To ensure compliance, patient aids must be administered by the appropriate healthcare professional.</p> <p>14.10 The tone of material must not cost unnecessary alarm or misunderstanding nor must it cause unfounded hopes of successful treatment to stimulate demand for prescription of a particular product.</p>	
<p>15.0 Access Program Guidelines</p> <p>PHAP recognizes that patients benefit from access programs and patient care initiatives that allow access to cheaper medicines for Filipino patients. On the other hand, the independence of healthcare professionals must be maintained such that no financial benefit or benefit-in-kind may be provided or offered to a healthcare professional in exchange for prescribing or recommending the product.</p>	<p>This Section is based on PHAP Memorandum Circular 001-2015 Amendments on the PHAP Code as Ratified During the February 26, 2015 GMM</p>

Also, such programs must encourage appropriate use for pharmaceutical products by supporting the qualified oversight by healthcare professionals over the prescribing and medication process. To ensure that these programs comply with existing and applicable legal and regulatory frameworks, the following should be observed:

1. Access programs or patient care initiatives may include a discount feature, whether through coupons or e-cards.

2. Such discounts through coupons or e-cards must be channeled through the physician and backed by a prescription. No such discount card or coupon can be given directly to patients.

3. Under no circumstances should the physician be compensated nor benefit from such discounts.

4. Access programs and patient care initiatives, particularly in implementing discount features, should be non-discriminatory. It must be made available to any or all physicians who may wish to pass them to patients.

5. The discount feature or scheme under any access program or patient care initiative should not be advertised to the patient in any form at the doctor's clinic, including the display of posters and/or leaflets.

6. The discount feature or scheme cannot be tied to sales promotion, raffles or promise of reward that may encourage self-prescription.

7. For purposes of accountability, access programs or patient care initiatives, with or without a discount feature and whether through coupons, cards or electronic versions thereof, must clearly identify the responsible company and relevant participating health product.

16.0 Administration of the Code

The administration of the Code shall be supervised by the Ethics Committee of the Association. The Committee in reaching a decision as to whether or not a breach has occurred may seek expert advice externally.

Complaints Handling Procedure

16.1 Intercompany Discussions First

Member companies are encouraged to settle matters among themselves before elevating the issue to the PHAP Ethics Committee.

16.2 Submission of Complaints

Complaints must be in writing or by e mail and must include:

Complainant details:

- The true identity of the complainant with a full mailing address (including fax number and email, if possible) for correspondence.

A private person or entity who lodges a complaint may request for anonymity. Industry complaints must be signed by the General Manager or a senior officer of the Company in violation: For each case, the identity of the company which is alleged to be in breach of the PHAP Code and the name of any product or products which are specifically involved.

- Summary: For each case, a brief description of the complaint with reference to the portion of the PHAP Code under which the complaint is being made (section and paragraph number).

- Reference material: For each case, a specific reference to the source of the advertisement/activity, which is the subject of the complaint, or printed material or other evidence. A copy of the material in question must be provided.

<p>•Date(s) and place(s): The date and place of the alleged breach of the PHAP Code.</p> <p>All communications should be addressed to:</p> <p>The Executive Director</p> <p>Pharmaceutical & Healthcare Association of the Philippines Rm. 502 One Corporate Plaza, A. Arnaiz Avenue, Makati City</p> <p>The PHAP Secretariat shall stamp and acknowledge receipt of the complaint.</p> <p>The PHAP Secretariat who shall also determine if such merit the attention of the EC may entertain inquiries and clarifications pertaining to the Code.</p>	
<p>16.3 Validation</p> <p>When a complaint alleging a breach of the PHAP Code is received by the PHAP Secretariat, it shall first validate the complaint within five (5) working days to ensure that:</p> <ul style="list-style-type: none"> • It appears to be genuine, submitted in good faith; • There is sufficient information to enable the complaint to be processed (Based on the requirements for the submission of complaints). <p>If the information provided in the complaint is inadequate, the complainant must provide additional information within the 5 working days allocated for Secretariat validation.</p> <p>Finally, if a complaint cannot be validated, it shall not be processed and the complainant must be notified accordingly.</p> <p>16.4 Notice</p> <p>Within five (5) working days from receipt by PHAP of the valid complaint, a copy, including any supporting evidence</p>	

(e.g. a copy of the advertisement alleged to be in breach of the PHAP Code), shall be sent to the General Manager and the Compliance Officer of the “Respondent Company”.

16.5 Response

The Letter to Respondent shall indicate the time within which a response must be made which shall be no more than fifteen (15) working days from Respondent’s receipt of the document. No extension of time shall be granted.

If Respondent fails to respond within the prescribed period, the complaint shall be submitted for resolution by the EC based on the evidence submitted by the complainant.

16.6 Resolution

Cases shall be decided within thirty (30) working days from receipt of Respondent’s reply, or if Respondent fails to submit a written response, from the lapse of the period for submitting such response.

If necessary, the PHAP EC may convene an experts’ panel to provide medical or technical advice and may therefore extend the timelines.

However, for all cases, the PHAP Ethics Committee must resolve the case and transmit its ruling to both the complainant and Respondent within sixty (60) working days from receipt of Respondent’s reply, or if Respondent fails to submit a written response, from the lapse of the period for submitting such response.

16.7 Appeal

The PHAP Ethics Committee shall not entertain any motions for reconsideration. The decision of the Ethics Committee shall be immediately enforceable. In the instance that either the complainant or the accused contests the decision, it may file an appeal within fifteen (15) working days to the PHAP Board of Trustees from receipt of the decision that in turn constitutes an Appeals Board.

<p>16.7.1 Appeals Board (AB)</p> <p>Decisions by the AB are absolutely final and executory.</p> <p>The composition of the AB shall be drawn from an independent pool of experts.</p> <p>An administration fee shall be charged to the party who files the appeal.</p> <p>All appeals shall be decided within thirty (30) working days from receipt of the appeal.</p>	
<p>16.8 Sanctions</p> <p>If a company is found in breach of the PHAP Code, company has ten (10) working days to provide written details of the action taken to comply with the ruling (“the Compliance Statement”).</p> <p>At the very least, the company will be asked to confirm that the activity or use of the material or program in question, and any similar material/program if not already discontinued or no longer in use, will cease immediately and that all possible steps will be taken to avoid a similar breach of the Code in the future.</p> <p>The Compliance Statement must be signed or authorized by the General Manager and must include the date on which the material was finally used or appeared and/or the last date on which the activity took place.</p>	<p>How much is the administration fee for appeals?</p> <p>The administration fee for appeals is P40,000 if the decision is reversed on appeal, this amount will be returned to the appealing party.</p>
<p>16.9 Penalty Scheme</p> <ul style="list-style-type: none"> • First offense shall be meted a fine of PHP 200,000.00. • Succeeding offenses of the same nature (e.g., interfering with HCP independence) or within the same section of the Code within a twelve month period shall be meted a fine of PHP 750,000.00 per offense. • Clean slate if no violations of the same offense are committed within a 12-month period. Reckoning date for all violations is the date when a decision was issued by the PHAP Ethics Committee. 	

<p>16.10 Publication of the Outcome</p> <p>A summary of the cases will be published on the PHAP website. The information disclosed will include a brief summary of the key facts and the results of the EC ruling and/ or the Appeals Committee. The respondent company, the complainant, and product(s) shall not be named.</p> <p>However, for companies with multiple violations involving any provision of the Code, the information on the identity of the company in breach, the name of any product, and other relevant information shall be disclosed.</p> <p>Moreover, the Headquarters of the company in breach shall be notified of the violation.</p> <p>A copy of the material to be published is provided to the respondent company for information only.</p>	
<p>17.0 Compliance Procedures</p> <p>It is the responsibility of PHAP members to ensure that an internal compliance procedure exists that strives for compliance with all provisions of the Code and the spirit it embodies. This procedure should be documented and provided to relevant employees to further enhance COP compliance.</p>	
<p>18.0 Amendments</p> <p>This Code may be amended by a simple majority vote of all the members present in a General Membership Meeting provided the meeting was announced at least two weeks in advance and the proposed amendments are included in the agenda.</p>	



PHARMACEUTICAL & HEALTHCARE
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APPENDIX 1

GUIDELINES ON COMMUNICATION OF PRESCRIPTION PRODUCTS TO THE GENERAL PUBLIC

DEFINITION OF TERMS

Advertisement:

Promotion of a product, service, advocacy or institution by way of paid placement through media (print, broadcast, billboards, collaterals) at a guaranteed target date or time. This includes any representation by any means whatever for the purpose of promoting directly or indirectly the sale or disposal of any pharmaceutical product.

Advertorial:

A paid advertising material in editorial format. An advertorial can be distinguished from a news release or feature article in that most of the time an advertorial material would contain at the bottom of the material the word "ADVT," which means advertising.

By-lined articles:

News articles, feature stories or health columns with the name of the writer displayed after the title of the story.

Infomercials:

Dissemination of information of a product, disease, clinical study or advocacy through non-paid media.

Locally generated news:

Press materials prepared and issued by the Philippine-based pharmaceutical company.

Mass Media:

Any publication, book, notice, handbill, poster, circular, pamphlet, letter, billboard, print medium, radio, television, cinema, mobile audiovisual unit or widespread medium of information directed at the lay public.

Press Release:

An official announcement or account of a news item circulated to the media without assurance that it will come out in a newspaper or magazine.

Prescription products:

BFAD-registered medicines or drugs dispensed by drugstores and pharmacies to patients with prescriptions. These are also known as "Ethical Drugs."

Promotion:

The practice of giving temporary additional value to a brand, product or service to achieve specific marketing objectives. This includes the distribution of free/sample pharmaceutical products.

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Tri-media advertisement:

Paid advertising placement using print, TV and radio.

Wire News:

Press articles generated by a wire agency.

THE GUIDELINES

1. Conform to FDA and local industry regulations.
2. Per DOH AO 65 Sec. 2.4, the pharmaceutical company that owns the pharmaceutical product and its Medical Director shall be responsible and accountable for the content of its advertisement and promotional materials. To be consistent, all materials and press releases should have the approval of at least the Medical Director.
3. Observe self-regulation in the following channels of communication and news trigger points:
 - a. Any form of tri-media advertisement is strictly not allowed per Section No. 3 of BFAD Regulation No.5 s. 1989. The only allowable channels of communication are press releases, editorials, health columns and features, and public service announcements per Section 4 of BFAD Regulation No.5 s. 1987.
 - b. For multi-national and foreign-owned companies: news coming from company headquarters,
 - The local subsidiary should filter or adapt International Headquarters news to local requirements.
 - Press information shall follow the company approval process Consistent with DOH AO 65 Sec. 2.4, the Medical Director should approve all outgoing press information.
 - It is advisable to also secure legal approval either through in-house legal counsel, a legal retainer or PHAP legal counsel.
 - c. Locally generated news.
 - This is allowable if consistent with PHAP Code.
 - However, this should go through medical approval or the appropriate company approval process. The company's Medical Director should approve all outgoing press information.
 - It is advisable to also secure legal approval either through in-house legal counsel, a legal retainer or PHAP legal counsel.
 - d. By-lined articles
 - PHAP does not have jurisdiction over third-party writers, health columnists and media spokes- persons.
 - Please refer to #4 below on ethics related to industry interactions.
 - e. Statements of Employees
 - Attributions, quotations and statements lifted out of an interview, lecture or media briefing are allowed as long as employee statements, whether direct or indirect, conform to ALL the prescribed guidelines.

- f. Media briefing (press conference, media RTD's, exclusive one-on-one interview)
- Press kits shall have the necessary medical approval. The Medical Director should approve all outgoing press information.
 - It is advisable to also secure legal approval either through in-house legal counsel, a legal retainer or PHAP legal counsel.
 - No product photos and product backdrops are allowed
 - PHAP Guidelines on "Communications with the General Public" shall be part of the press kit.
- g. Global and Regional Media Conference
- The invited journalist/s shall be issued press materials complying with Section 5 (Acceptable and Recommended News Content/Format). Since this is an international event, it is the responsibility of the Philippine-based pharmaceutical company to ensure compliance with the guidelines. (Refer to the Philippine Journalists Code of Ethics)
- h. "Online" (internet) news and promotion
- This should apply to local broadsheets with online versions (e.g., inquirer.net, mb.com.ph., philstar.net, bworldonline.com, etc.). Guidelines a, b, and c are to be applied for online news.
- i. Wire news
- Wire news is acceptable. PHAP has no jurisdiction over wire news independently picked up by media. However, to be legitimate, wire news articles should have been properly sourced from the news agency (e.g., AP, Reuters).
 - Feeding of news on competitive products is considered unethical.
- j. Pre-arranged interviews and guesting (TV, radio and print)
- The Medical Director should approve script guides and proposed scripts.
 - It is also advisable to secure legal approval either through in-house legal counsel, a legal retainer or PHAP legal counsel.
 - Backdrops with brand mention for TV, and sound bites with brand mention for radio are not allowed.

Please refer to Guideline #4 (Ethics on Industry Interactions).

4. Ethics on Industry Interactions with Media and Third-Party Spokespersons

- It is unethical to pay physicians and media to influence professional or public opinion. Specifically, no commissions or payments shall be given for articles, editorials or medical journal reviews that are actually written by industry or public relations firms in an attempt to manage the press on certain products and services.

5. Acceptable and Recommended News Content/Format

- Infomercials covering medical and healthcare topics and treatment options are permitted as long as its content: (a) is medically sound; (b) does not encourage self-medication; (c) directs readers to consult a doctor; and (d) includes treatment options that are balanced with information on contraindications, precautions, warnings, and/or side effects.
- Information material should encourage patients to seek further information or explanation from the appropriate healthcare professional.
- The material should be current, accurate, and balanced.
- The material must contain a statement directing the patient to seek further information from his or her doctor.
- BFAD Sec. 4 Press releases, editorials, health columns and features and public service announcements on health and medicines shall not specify brand/trade names. Generic names, however, are permissible. For prescription drugs, it should be clearly stated that this product can be bought only with a prescription and that a doctor's advice should be sought.

TABLE 1

Engagement	Description	Maximum Honorarium (net of tax)	
		In-Base (Php)	Out-Base (Php)
Symposium	# of HCPs should be 50 and above	23,000	28,000
Small Group Meetings	# of HCPs should be at least 10	13,000	18,000
Focused Group Discussion	# of HCPs should be at least 5	10,000	N.A
Local Experts Input, Advisory Board, Steering Committee, Faculty Meetings, etc.	Must involve established Faculty/National KOLs with a set agenda before the meeting (Member companies to exercise reasonable discretion on the appropriateness of the amount on the basis of time spent, nature of discussion, materials reviewed for the meeting, etc.)	23,000	
Other types of Lectures	Lay-forum, etc	13,000	
Moderator, reactor, etc.	Symposium, workshop, etc.	13,000	
Module Development	Member companies must have reasonable discretion on the appropriateness of the amount depending on the extent of work done, i.e., whether the module is an enhancement of an existing module, etc.	28,000	

PHAP recommends the amounts in table as the maximum rates for HCP honoraria for common events conducted within the Philippines.

These recommendations are not intended to restrict member companies from providing different rates as long as they are not excessive and they reflect the fair market value of the services provided, taking into consideration such factors as the nature of the services, therapeutic area of expertise, experience level/qualification of the HCP engaged, number of HCPs in the same level of expertise, complexity of the subject matter, duration of the event and the number of event participants.

HCPs who conduct lectures for international event held in the Philippines are entitled to an honoraria based on the prevailing fair market value relative to the same measures used for non-Filipino HCPs in the same event.



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11. Calmoseptine Phils.,
12. Dentsply Phils. Inc.
13. Eli Lilly Philippines Inc.
14. Galderma Philippines
15. GlaxoSmithKline Phils.,
16. HI-EISAI Pharmaceuticals, Inc.
17. Hizon Laboratories, Inc.
18. Johnson & Johnson (Philippines), Inc.
19. Medicomm Pacific Inc.
20. Mercury Drug Corporation
21. Merck Inc. Philippines
22. Merck Sharp & Dohme (I.A.) LLC
23. Metro Drug, Inc. Philippines
24. Mundi Pharma Distribution GmbH Philippines
25. Novartis Healthcare Philippines, Inc.
26. Novo Nordisk Pharmaceuticals (Phils.) Inc.
27. Panpharma Healthcare & Pharmaceuticals Inc.
28. Pfizer Inc. Philippines
29. PharmAsia-Cuvest, Inc.
30. Philusa Corporation
31. Qualimed Pharma. Inc
32. Quintiles IMS Health Philippines, Inc.
33. Roche (Philippines) Inc.
34. Rudolf Lietz, Inc.
35. Sanofi-aventis Philippines, Inc.
36. Swisspharma Research Laboratories, Inc.
37. Takeda Healthcare Philippines, Inc.
38. TGP Pharma Inc.
39. Vizcarra Pharmaceutical Inc.
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