



PHARMACEUTICAL & HEALTHCARE
ASSOCIATION OF THE PHILIPPINES



Foreword

PHAP Code of Practice aligns with the PhRMA, EFPIA and IFPMA Joint Guidance on Virtual International Medical Congresses Impacted by COVID-19, the 2020 2019 Amended Code of Practice of the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) and adopts in full and with Administrative Order No. 2015-0053 Implementing Guidelines on the Promotion and Marketing of Prescription Pharmaceutical Products and Medical Devices, 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, professional requirements and international guidelines on face-to-face and virtual interactions.

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

September 2020

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

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

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

September 2020

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.

President: Dr. Beaver Tamesis
(Managing Director, Merck Sharp & Dohme,
(I.A) LLC)

Vice President: Mr. Ramonito Tamos
(President and Managing Director,
Merck Inc. Philippines)

Treasurer: Mr. Raymund Azurin
(Senior Vice President Sustainability &
Government Affairs, Zuellig Pharma
Asia Pacific)

Trustees: Mr. Teodoro B. Padilla (Executive Director)

Ms. Kara Brotemarkle
(General Manager, Roche (Philippines), Inc.)

Mr. Yee Kok Cheong
(General Manager, Boehringer Ingelheim)

Ms. Jannette Jakosalem
(Chief Executive Officer, Metro Drug, Inc.)

Ms. Amal Makloufi Benchouk
(General Manager, Sanofi)

Mr. Andreas Riedel
(Country Manager, Pfizer Inc.)

September 2020

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.

Chairman

Ernesto O. Domingo, MD
Professor Emeritus, UP College of Medicine
Ramon Magsaysay Awardee

Vice Chairman

Reiner W. Gloor
PHAP Adviser

Members

Cristobal C. Dumo, Jr., MD
Chief of Section of Infectious Diseases,
Department of Medicine
Victor R. Potenciano Medical Center
Assistant Professor 3
St. Luke's College of Medicine

Yolanda Robles, MD
Dean, University of the Philippines
College of Pharmacy
Executive Vice President, Philippine
Pharmacists Association

Manuel M. Dayrit MD. MSc
Dean, Ateneo School of Medicine
and Public Health
Former Department of Health Secretary

Benito L. Teehankee, Ph.D
Chairman, Management & Organization
Department, College of Business,
De La Salle University

Madeleine Valera, MD, MScIH
Former Department of Health
Undersecretary for Health Policy,
Finance & Research Development

Technical Adviser on Ethics Matters
Francisco P. Tranquilino, MD
Associate Professor 7, UP College of Medicine

Teodoro B. Padilla
Executive Director
Pharmaceutical and Healthcare Association of the Philippines (PHAP)

September 2020

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 2020

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 2020



PHARMACEUTICAL & HEALTHCARE
ASSOCIATION OF THE PHILIPPINES

Table of Contents



Table of Contents

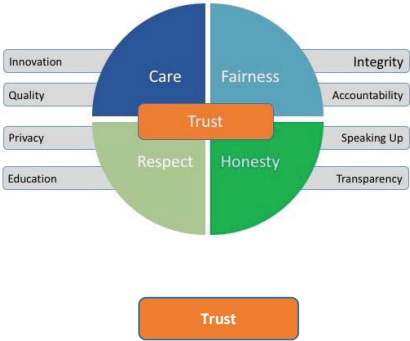
Ethos	15
Guiding Principles	18
Code of Pharmaceutical Marketing Practices	19
2.0 Medical Information and Promotional Claims	23
3.0 Product Information	25
4.0 Content of Promotional Materials	25
5.0 Educational Items	30
6.0 Items of Medical Utility	30
7.0 Promotional Aid	31
8.0 Other Communication Channels	32
9.0 Medical Representatives/Professional Service Representative (PSR)	32
10.0 Product Samples	34
11.0 Events and Meetings	34
11.12 Virtual Engagements	42
12.0 Independence of Healthcare Professionals	44
13.0 Clinical Studies	44
14.0 Post-Marketing Surveillances	46
15.0 Honoraria	47
15.2 Virtual Honoraria	48
16.0 Patient Organization, Patients, Patient Support Programs	48
16.4.1 Virtual Patient Support Programs	51
17.0 Communications With The General Public	51
18.0 Access Program Guidelines	53
19.0 Administration of the Code	54
20.0 Publication of the Outcomes	58
21.0 Compliance Procedures	58
22.0 Amendments	58
Appendix	59
FAQ	66


September 2020



PHARMACEUTICAL & HEALTHCARE
ASSOCIATION OF THE PHILIPPINES

Code of Practice

Proposed Amendment/ Alignment with PHAP Code	
PHAP Code	Explanatory Notes
<p>PHAP Ethos</p> <p>The Pharmaceutical and Healthcare Association of the Philippines (PHAP) as a member of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) fully subscribes to the IFPMA Ethos that serves as foundation of the PHAP Code of Practice. ^[SEP]</p> <p>The Ethos sets out the foundation to inform the 2019 IFPMA Code of Practice which applies to the conduct of IFPMA member companies and anyone acting on their behalf. The overarching values of trust, care, fairness, respect and honesty guide their actions. This set of core values and principles helps ensure that their interactions with healthcare professionals and the broader health community are appropriate and in line with ever-changing society's expectations. The Ethos is the baseline from which IFPMA members work: It underpins the rules and provides a framework to behave with integrity no matter how testing the circumstances. ^[SEP]</p> 	<p>Source:</p> <p>International Federation of Pharmaceutical Manufacturers (IFPMA). <i>Code of Practice</i>, 2018, p.4-8 ^[SEP]</p> <div data-bbox="675 1032 1066 1322"> <div>Trust</div> <div>Act with integrity and honesty to improve patient care and build trust with those we serve and to respect the independence of healthcare providers, patients and other stakeholders</div> <div>Care</div> <div>Protect the safety of those who use our products- from the conduct of clinical trials and throughout the product life cycle.</div> </div>

	<div data-bbox="652 322 1002 456"> <p>Innovation</p> <p>Improve global health through innovative products and services, upholding the highest ethical, scientific and medical standards.</p> </div> <div data-bbox="652 474 1002 609"> <p>Quality</p> <p>Commit to providing high quality products that have proven clinical efficacy and have a reliable safety profile.</p> </div> <div data-bbox="641 698 993 833"> <p>Fairness</p> <p>Support and respect fair trade practices and open competition.</p> </div> <div data-bbox="641 851 993 1030"> <p>Integrity</p> <p>Act responsibly, ethically, and professionally. Do not offer promise, provide or accept anything of value in order to inappropriately influence a decision, gain an unfair advantage.</p> </div> <div data-bbox="641 1048 993 1227"> <p>Accountability</p> <p>Be accountable for our actions and decisions, including the appropriate oversight of external third parties that act on our behalf.</p> </div>

<div data-bbox="331 218 505 390"> <p>Respect</p> </div> <div data-bbox="316 689 518 885"> <p>Honesty</p> </div>	<div data-bbox="665 209 856 259"> <p>Respect</p> </div> <div data-bbox="665 259 1031 378"> <p>Respect all people and embrace a culture of diversity and inclusion. Protect the environment. Treat animals under our care responsibly.</p> </div> <div data-bbox="665 390 856 440"> <p>Privacy</p> </div> <div data-bbox="665 440 1031 528"> <p>Respect data privacy rights and appropriately manage and protect personal information.</p> </div> <div data-bbox="675 557 865 607"> <p>Education</p> </div> <div data-bbox="665 607 1031 695"> <p>Support the advancement of the scientific and medical education for the ultimate benefit of the patients.</p> </div> <div data-bbox="675 736 865 786"> <p>Honesty</p> </div> <div data-bbox="665 786 1031 890"> <p>Ensure truthful and balanced communication with governmental authorities, healthcare professionals, patients and other stakeholders</p> </div> <div data-bbox="675 903 865 953"> <p>Speaking Up</p> </div> <div data-bbox="665 953 1031 1055"> <p>Foster a culture in our respective organizations where concerns are shared openly and honestly so that we learn from mistakes and continuously improve.</p> </div> <div data-bbox="675 1082 865 1132"> <p>Transparency</p> </div> <div data-bbox="665 1132 1031 1234"> <p>Advance science and patient care by sharing industry-sponsored clinical trial data in a responsible, accurate and appropriate manner.</p> </div>
---	--

<p>PHAP Guiding Principles On Ethical Conduct and Promotions</p> <p>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"> • The healthcare and well-being of patients are the first priority for pharmaceutical products and medical devices companies. • Pharmaceutical and medical devices companies will conform to high standards of quality, safety and efficacy as determined by regulatory authorities. • 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). • Pharmaceutical and medical devices companies are responsible for providing accurate, balanced, and scientifically valid data on products. • 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. • Pharmaceutical and medical devices companies will respect the privacy of healthcare professionals and patients' personal information obtained during face-to-face and virtual engagements. • 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. <p>Pharmaceutical and medical devices companies are committed to the transparency of industry sponsored clinical trials in patients.</p> <p>PHAP Member Companies should adhere to both the spirit and the letter of this Code and ensure that all relevant personnel are appropriately trained.</p> <p>The PHAP Code of Practice covers not only member companies but also local subsidiaries of IFPMA member companies.</p>	
--	--

1.1 Scope of Coverage

1.1 Scope of Coverage

The face-to-face and virtual promotion and advertisement of pharmaceutical products and medical devices directed to HCPs are deemed to fall within the scope of the Code.

1.2 Public Sector Relationships and Procurement

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.

Companies must provide accurate and balanced information to the Government.

Companies and government officials should ensure that their relationships and fee-for-service arrangements comply with government ethics rules or procedures.

Adherence to Principles

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.

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.

Company initiated events are activities independently organized by companies, either on its own or through a third party on behalf of the Company that provide product, disease awareness, or other product-related information to HCPs for

1.1 The Code also covers promotion and advertisement of over the counter medicines and medical devices to healthcare professionals.

Examples of company-initiated events:

- Product presentation
- Round table discussion
- Focus Group Discussion

<p>promotion or non-promotional reasons. The Company has control over the agenda, location, HCP selection, speakers, or management of the meeting and event.</p> <p>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.</p> <p>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.</p> <p>Events means all promotional, scientific, or professional meetings, congresses, conferences, symposia and other similar events, (including, but not limited to advisory board meetings, visits to research or manufacturing facilities and planning or investigator meetings for clinical trials and non-intervention studies (each an "Event") organized or sponsored by or on behalf of a company.</p> <p>Exhibition Stands are areas where pharmaceutical companies (and other organizations) can display their product material to delegates in the commercial booth and their scientific material in the medical exhibition area.</p> <p>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.</p> <p>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</p>	<ul style="list-style-type: none"> • Product Launch • Advisory board • Symposium • Clinical trial meetings • Congresses • Investigator meetings
--	---

<p>through which one or more health professionals or other relevant decision-makers provide services.</p> <p>Items of Medical Utility means items that can be offered to Healthcare Professionals that should not offset routine business practices and are beneficial to enhancing the provision of medical services and patient care. These are medical items or devices that provides benefits to patient care. These are non-promotional items.</p> <p>"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.</p> <p>Medical Congress is a scientific meeting organized by a medical association/society etc. for their members with the opportunity for industry to participate in the form of exhibition (medical and commercial), satellite symposia etc.</p> <ul style="list-style-type: none"> ○ The medical association/society is the owner of the congress and responsible for attendee management, access, and other relevant criteria, e.g. the scientific agenda. ○ The Congress gathers a multinational group of medical experts and professionals with the objective to increase the knowledge about and expertise in a disease state and treatment, to facilitate exchange and ultimately to advance patient care. ○ The delegates usually comprise of HCPs, researchers and other individuals who work in the healthcare and/or research environment. <p>"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.</p> <p>"Promotion and advertisement" means any activity undertaken, organized or sponsored by a member company, which is directed at HCPs to promote the</p>	
--	--

<p>prescription, recommendation, supply, administration or consumption of its pharmaceutical product(s) through any medium, including the internet.</p> <p>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> <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>Satellite symposium is a Company activity which occurs immediately prior, during or immediately after the main scientific program in the context of a congress.</p> <p>Promotional Aid means a non-monetary item given for a promotional purpose and should be relevant to the practice of the Healthcare Professional and not for personal benefit.</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>Virtual engagements are activities that use virtual or digital platform in lieu of face-to-face interactions. These virtual platforms may include but not limited to emails, text messages, messenger applications, virtual meeting applications, social media and webinar facilities. Virtual engagements include both 3rd party and company-sponsored events</p> <p>Virtual (Medical) Congress is a congress where all activities are virtual/digital without an in-person event linked to it. Companies have the opportunity to participate in the form of virtual exhibition stands as well as virtual satellite symposia.</p>	<p>Examples of virtual platforms: Emails, SMS, Viber, Whatsapp, Telegram, Googlemeets, Webex, Zoom, Facebook, Youtube, Microsoft Teams, etc.</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</p> <p>"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>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</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>2.2 Pre-Approval Communications and Off-Label Use (IFPMA p. 5)</p> <p>No pharmaceutical product shall be promoted for use until the requisite approval for marketing for such use has been given.</p> <p>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.</p> <p>2.3 Substantiation (IFPMA p. 5)</p> <p>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</p>	<p>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> <p>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>
--	--

<p>data, which are appropriate to the source of the inquiry.</p> <p>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.</p> <p>2.4 New Products</p> <p>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.</p> <p>2.5 Medical Ethics</p> <p>No PPPMD company shall employ or contract any HCP or health worker to promote, advertise or endorse any pharmaceutical product or medical device in mass media, print, audio visual display or social media. (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 HCPs. 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 (DOH AO 2015-0053)</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.</p> <p>4.2 General requirements of promotional material:</p> <ul 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 	

<p>Order 65 s.1989, specifically under Section 3 on Guidelines on advertisement and promotions to implement the Generics Act 1988, including any amendment thereto.</p> <ul style="list-style-type: none"> 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. <p>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:</p> <ul style="list-style-type: none"> 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 <p>4.4 Quotations</p> <ul style="list-style-type: none"> 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. <p>4.5. Data from clinical studies</p>	
---	--

<p>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.</p> <p>b. Clearly mark in-vitro and animal tests data as such.</p> <p>c. The following information to where the data can be shall include:</p> <ol style="list-style-type: none"> 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 <p>4.6. Visuals, graphics and tables</p> <p>a. Visuals, such as graphics and tables, shall be consistent with the text to convey the information accurately.</p> <p>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.</p> <p>4.7. Unpublished data</p> <p>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.</p> <p>b. Prior to printing of promotional material, the complete length of publications and manuscripts for publication or in press shall be available on hand.</p> <p>4.8. Claims</p> <p>a. All claims shall be accurate and substantiated from legitimate sources and be made available upon request.</p> <p>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.</p>	
---	--

<p>c. Requirements for Comparative Claims:</p> <p>c.1 Claims properly supported by scientific data and in accordance with local regulations may be allowed;</p> <p>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;</p> <p>c.3. Superiority claims may be allowed if supported by competent (measuring up to all requirements) and well-controlled clinical trials; and</p> <p>c.4 Claims related to difference in efficacy between drugs may be allowed if it is clinically relevant and statistically significant ($p < 0.05$).</p> <p>Pursuant to Section 2 of DOH AO 2015-0053:</p> <p>4.9 Promotional Information and Activities</p> <p>a. Information provided by (PPPM) manufacturers and distributors to health professionals regarding their products shall be restricted to evidence-based scientific data.</p> <p>b. Promotional materials provided by industry to any HCP shall ensure the following:</p> <ol style="list-style-type: none"> 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 <p>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:</p> <ol style="list-style-type: none"> (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. 	
--	--

<p>d. Promotional or marketing materials of PPPMD companies using citations, quotes or statements lifted from medical literature, lectures, presentations, or similar sources of information shall not be changed, distorted or taken out of context.</p> <p>The following claims and/or comments shall be prohibited:</p> <ol style="list-style-type: none"> 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. <p>Other Prohibited Words and Phrases are:</p> <ol style="list-style-type: none"> 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) <p>4.10 Virtual Promotional Materials</p> <ul style="list-style-type: none"> • Virtual promotional materials must be accompanied by a statement indicating the countries in which the medicinal product is registered, and by an explanatory statement indicating that registration conditions differ internationally. • Additionally, the statement should be prominently displayed (e.g. via a pop-up box or alternative display) informing delegates to refer to prescribing information from their home country as information may be different for each country 	<p>Sample Explanatory Statements/ Disclaimer:</p> <ul style="list-style-type: none"> • "You are viewing an International Virtual Congress run by [society name] and provided to international HCPs from around the world. Please note that prescribing information provided here may vary depending on local approval in each country. For purposes of [congress name], best efforts were undertaken by [society name] and congress sponsors to ensure compliance with [relevant code], however, you should review your local
--	--

<ul style="list-style-type: none">Companies should ensure that a process is in place to <i>confirm participants' status as HCPs/Non- HCPs</i> (patient advocates, journalists, industry representatives, etc.).<ul style="list-style-type: none">Make reasonable efforts to restrict access to promotional material to HCPs only, where required by applicable rules and regulations.Where the medical association's platform does not have a categorization capability, Companies should consider alternative mechanisms to enable attendee classification for their promotional events. <p>5.0 Educational Items</p> <p>PPPMD companies may occasionally provide textbooks and journal subscriptions to Healthcare Organizations (HCOs) to benefit patients or serve a genuine educational function for the HCO.</p> <ul style="list-style-type: none">Guidance on values: <p>One Journal subscription may be provided to HCOs per year provided that it is of reasonable value.</p> <p><u>A medical or scientific book may be given per clinical department, hospital or HCO department per year and should not exceed Php 8,000.</u></p> <p>6.0 Items of Medical Utility to enhance the Provision of Medical Services and Patient Materials</p> <ul style="list-style-type: none"><u>Items of medical utility</u> may be offered or provided by member companies if such items are of modest value, do not offset routine business practices and are beneficial to enhancing the provision of medical services and patient care.They should not be offered <u>more than twice a calendar year</u>, even if each individual item is appropriate.Guidance on values:	<p>prescribing information and consult directly the local affiliate of the relevant Company to address any questions."</p> <ul style="list-style-type: none">"The materials for [PRODUCT(S)] contained in this virtual exhibition are approved for use only in [COUNTRY]. Prescribing information may vary depending on local approval in each country. Therefore, before prescribing any product, always refer to local materials such as the prescribing information and/or the Summary of Product Characteristics (SPC)."
---	--

Q. What are examples of items of medical utility which offset business practices?

<p>Maximum value for items of medical utility should not exceed Php 8,000.00</p> <ul style="list-style-type: none"> Materials provided to HCPs for their education or for the education of patients on disease and its treatments may be offered by member companies provided that the items are primarily for educational purposes and do not have independent value. Informational and educational items provided to HCPs for patient use can include the company name, but must not be product branded, unless the product's name is essential for the correct use of the item by the patient. As a general rule, items of medical utility and patient materials can only include the company name, unless the product's name is essential for the correct use of the item by the patient. 	<p>A. Items such as stethoscopes, surgical gloves, blood pressure monitors and needles are examples of routine business expenses, and they are expected to be supplied by the HCPs themselves or their employers.</p>
<p>7.0 Promotional Aid</p> <ul style="list-style-type: none"> A promotional aid is a non-monetary item given for a promotional purpose, which does not include printed promotional materials. Providing or offering them to HCPs in relation to the promotion of prescription-only medicines and medical device is prohibited. Guidance on values: Promotional aids of minimal value and quantity may be provided or offered to HCPs solely for the promotion of <u>over-the-counter medicines</u> if relevant to the practice of the HCP. Maximum value for promotional aid should not exceed Php 1,000.00 	<p>Q. Section 5.0 prohibits promotional aids for prescription-only medicines. Does this also apply to the provision of pens and notepads in the context of CMEs/ conference set-up?</p> <p>A. No, pens and notepads can be provided to HCPs in the context of CMEs/ conference set-up as long as they are company branded only, of minimal value and only the necessary quantity for the purpose of the CME are distributed as part of conference table arrangement. <u>Pens and notepads will not be allowed in prescription medicine and medical device booths.</u></p>

<p>8.0 Other Communication Channels</p> <p>8.1 These channels include all non-face-to-face or virtual engagements/ interactions like social media, digital meeting applications, email, fax, SMS (Text messages), and webinars.</p> <p>These forms of communications must comply with all relevant provisions of the Code and data privacy protection measures as prescribed by the Data Privacy Act, and applicable rules and regulations issued by the National Privacy Commission.</p> <p>PHAP members are requested to review and evaluate the privacy notices and agreements of these virtual platforms or applications and evaluate if these meet data privacy protection standards to safeguard healthcare professionals and patients' personal and sensitive information.</p> <p>8.2 These communications should be sent only to those categories of healthcare professionals whose need for, or interest in, the particular information can be reasonably assumed. Requests to be removed from promotional mailing or any virtual / digital platform lists must be complied with promptly, and no name should be restored except upon specific request or with written permission.</p> <p>8.3. Mailing or virtual / digital platform lists should be kept up-to-date.</p> <p>8.4 Exposed mail, including postcards, envelopes, wrappers, emails and any digital form 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>Examples of virtual channels/ platforms: Emails, SMS, Viber, Whatsapp, Telegram, Google Meet, Global Meet, Hangout, Webex, Zoom, Facebook, Youtube, Microsoft Teams, etc.</p>
<p>9.0 Medical Representatives/ Professional Service Representatives (PSR)</p> <p>9.1 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>9.2 Members have a responsibility to maintain high standards of continuing competency training for representatives and shall be required to conduct the</p>	<p>9.0 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>

<p>mandatory courses under the Integrity and Proficiency Program in the Pharmaceutical Sector (IPPS) or its equivalent.</p> <p>9.3 Medical representatives/ Professional Service Representatives should, at all times, maintain a high standard of ethical conduct in discharging their duties.</p> <p>9.4 Medical Representatives/Professional Service Representatives should complete the training and pass the assessment under the IPPS.</p> <p>9.5 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.</p> <p>9.6 Conduct of Training of PPPMD Company Representatives</p> <p>a. Personnel employed as medical or sales representatives shall comply with existing Philippine Laws:</p> <ol style="list-style-type: none"> 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 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</p>	
--	--

<p>representatives with patients are strictly prohibited. (DOH AO 2015-0053 Sec 12). Compliance with the Data Privacy Act of 2012 should be observed at all times.</p>	
<p>10.0 Product Samples</p> <p>10.1 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>10.2 The quantity of samples given should be appropriate for HCPs to:</p> <p style="padding-left: 40px;">10.2.1 Initiate therapy; and/or 10.2.2 Gain clinical experience with the product.</p> <p>10.3 Product samples may be given for humanitarian reasons, but dispensing must be under the supervision of a qualified HCP</p> <p>10.4 Product samples must be accompanied by product inserts</p> <p>10.5 Product samples must comply with the labeling requirements of FDA, and must be clearly marked "Physician's Sample - Not For Sale."</p> <p>10.6 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>10.7 Samples should not be used as payment for services, return for favorable treatment, or other inappropriate inducements. (MCP, p. 8)</p> <p>10.8 Samples are duly acknowledged by the HCP and HCO (DOH AO 2015-0053 Sec 9, Letter A)</p>	<p>FDA Memo 2018-006 and Republic Act 10918 (Pharmacy Law) Section 34:</p> <p>Pharmaceutical products classified as antimicrobials, including anti-TB medicines and other classifications of medicines, as may be prescribed by the FDA, shall not be given or distributed as physician's samples.</p>
<p>11.0 Events and Meetings</p> <p>11.1 General Guidelines</p> <p>These requirements shall apply to face-to-face and virtual meetings; thus require that support and attendance be based on the event's educational value, considering the educational program, overall cost, nature of the audience, and cybersecurity and privacy arrangements, with attention paid to the overall</p>	

<p>impression given by all the various arrangements.</p> <p>Virtual engagement guidelines are specified in Section 11.12.</p> <p>11.1.1 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>11.1.2 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>11.2. Appropriate Venue</p> <p>All Events organized or sponsored must be held in an appropriate venue that is conducive to the scientific or educational objectives and the purpose of the Event or meeting. The meeting facilities including exhibition should only be accessible to the intended audience.</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>Likewise, hotels and establishments that operate, or have a third party-operated recreational, entertainment or leisure facility such as country clubs, golf clubs, sports clubs as well as resorts and casino or is attached to such facilities are considered inappropriate.</p> <p>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</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.</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> <p>Guidelines on venue appropriateness shall also apply to sponsorship of hotel accommodation of participants who will be attending the scientific or educational events.</p>
--	---

<p>under the circumstances and likewise taking into consideration the time constraints.</p> <p>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 preferably not coincide 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.</p> <p>The location is appropriate in respect to the geographical scope of the event.</p> <p>11.3 Events</p> <p>1. Symposium and Congress</p> <p>General Guidelines:</p> <p>Companies may support seminars, scientific meetings and third party conferences provided:</p> <ul style="list-style-type: none"> 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 	
--	--

<p>conflict of interest prior to topic presentation during the event.</p> <p>A. Company Organized</p> <ul style="list-style-type: none"> • Product presentation • The following are examples of company organized events. • Product presentation • Round table discussion • Focus Group Discussion • Product Launch • Advisory board • Symposium • Clinical trial meetings • Investigator meetings • Tactical activities <p>B. Third Party</p> <p>B.1 HCP/Medical Societies - Member companies should not specifically support:</p> <ul style="list-style-type: none"> • 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. <p>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> <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</p>	
--	--

when their facility is used as its venue. (Adopted from DOH AO 2015-0053)	
B.4. Pharmacists/Pharmacy clerks in their capacity as HCPs. 11.4 Exhibit Booths Exhibit booths <u>of prescription medicines and medical device</u> 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 8.4.1 Raffle activities will not be allowed 8.4.2 Educational activities may be conducted in booths.	
11.5 Support for Continuing Professional Development (CPD) General Guidelines: The purpose of any continuing professional development activity shall be to provide additional and updated information to HCPs that can contribute to the improvement of patient care. PPPMD companies shall develop objective criteria for making CPD grants to ensure that programs funded are bona fide and quality educational programs. The financial support provided shall not be an inducement to prescribe to recommend a particular pharmaceutical product or medical device or any course treatment. a. Industry sponsorship of HCPs to events involving foreign/local travel shall be allowed but subject to the following conditions: 1. The purpose of the event is to provide scientific or educational information; 2. The travel is justified because: (a) the event is held outside of the sponsored HCP's place/country of practice, and/or it makes greater logistical or security sense to hold the event in another location/country; or (b) in the exceptional circumstances where 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 or	Adapted DOH AO 2015-0053 Sec 8, Letters A, C, D, E

<p>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 PPPMD 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 PPPMD Company.</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. 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 an HCP 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><i>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.</i></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>
<p>11.6 A pharmaceutical company is allowed to sponsor</p>	

<p>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>11.7 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>11.8 Service Provider</p> <ol style="list-style-type: none"> Speaker Consultants Adboards Others <p>General Guidelines:</p> <p>11.8.1 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>11.8.2 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</p>	<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>the nature of services rendered and payment for such:</p> <p>a. Criteria for consultant selection is based on identified need and expertise;</p> <p>b. Contracting PPPMD company keeps a record of all transactions;</p> <p>c. Compensation for said services is reasonable and reflect the fair market value for said services;</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>f. A healthcare professional may be a lecturer, moderator, or speaker during CME activities and shall use only generic names when referring to pharmaceutical products during his presentation. Only the names of the pharmaceutical or health product company may be posted in the main session <u>for medical society or third party organized events</u>. The posters, pamphlets, brochures, stickers, advertisements or other similar character containing the names of the medicines or devices shall be posted <u>only</u> in designated areas.</p>	
<p>11.9 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> <p>a. Detailing, Product Presentation b. Focus Group Discussion c. Others</p> <p>11.10 Hospitality & Meals</p> <p>Meals with HCPs</p> <p>Member-companies are required to establish cap</p>	<p>9.9 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><i>Can medical representatives exceed the meal</i></p>

<p>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>11.10.1 Provision of Meals for Virtual Meetings/ Company organized meetings</p> <ul style="list-style-type: none"> • Meals may only be provided under the following condition: <ul style="list-style-type: none"> ○ At least 5 healthcare professionals are gathered in same hospital-setting or venue for meetings, continuing medical education, etc. ○ It is imperative for member companies to establish monitoring and control in ensuring that HCPs provided with hospitality attended the event. A Company should consider the policies and guidelines of healthcare institutions or facilities regarding utilization of contactless delivery services, food handling and other limitations on food sharing. ○ However, meals should not be provided where prohibited by the policies of the healthcare institution or facility. • Delivery of meals to individual healthcare professionals, especially in their residence will not be allowed 	<p><i>cap for tactical activities but only be reimbursed the maximum allowable amount?</i></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>11.12 Virtual Engagements</p> <p>The following are guidelines on local, national, and international meetings, organized by third parties, providing funding to assist in the medical education of HCPs, sponsorships to medical societies organizing events, hiring of exhibition space, support of speakers.</p> <p>Companies should also ensure that they are aware of and comply with the guidance issued by medical associations/societies etc. for organizing Virtual</p>	

<p>Congresses.</p> <p>11.12.1 Virtual CME/ Scientific Congress Access and Promotion</p> <ul style="list-style-type: none"> • Congress attendees should sign a <i>digital consent</i> indicating <i>awareness/acknowledging</i> Virtual Congress terms and conditions, such as <i>specific permission to access different virtual areas</i> (lectures, commercial expositions, social engagement sites, the basis of promotional material development, etc.). • Even if this is the responsibility of the medical association/society, companies need to be aware of the content of these kinds of Explanatory Statements/ Disclaimers. • Companies should explore putting in place <i>systems to appropriately address the situation where HCPs view materials from countries other than their own.</i> • Of particular concern is <i>potential promotion directed to people not qualified to receive such content and promotion of unlicensed medicines and/or indications.</i> • A Company sponsoring/collaborating with a booth at the virtual exhibition area should be able to <i>identify those wishing to view its booth (HCP or Non-HCP)</i> and therefore determine what information will be appropriate. • Companies and medical associations/ societies (congress owners) are strongly encouraged to work together to share experiences and where possible <i>jointly develop standards</i> for all to follow. • Only company logos will be allowed in virtual CMEs/ Scientific meetings interface. • Add virtual booth system including specific time slots to enable access of participants only during breaks. <p>11.12.3 Support for Virtual Continuing Professional Development/ Sponsorships</p> <ul style="list-style-type: none"> • Sponsorship of HCP in virtual platforms will allow registration of unlimited number of participants with company internal guidelines and 2x a year limit for both international/regional. 	<p>The use of Youtube live and Facebook live are discouraged for CMEs since these risk an exposure to unintended audience (public). Access to CMEs should be limited to healthcare professionals.</p>
--	---

<p>11.12.4 Sponsorship of Virtual Webinars</p> <p>Sponsorship of virtual conference/meeting platforms (i.e. subscription fees) for a particular event, such as hosting a webinar for institution/hospital/department will be allowed. Paying for personal/individual, medical society and hospital department virtual platform monthly or year-round subscription fees will not be allowed.</p>	<p>Similar to face-to-face local CMES, HCPs should shoulder registration fees.</p>
<p>12.0 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, 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>12.1 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>10.1 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>13.0 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</p>	<p>How does one ensure transparency in the conduct of Clinical trials?</p> <p>As stated in FDA Circular (2012-007) which</p>

<p>locally or outside the country.</p> <p>13.1 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>13.2 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>13.3 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>13.4 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>13.5 Studies in humans must not have the promotion of products as their purpose. Its implementation cannot be used as disguised promotions.</p>	<p>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 wit:</p> <ul style="list-style-type: none"> • "C. Mandatory Inclusion of Clinical Trials in the Philippine Trial Registry. All Clinical Trials are to be uploaded in the Philippine Clinical Trial Registry. • 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. • 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>13.6 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>13.7 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>13.8 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>13.9 Sponsorship to clinical trial investigators'</p>	

<p>meetings and presentations is allowed subject to the following provisions: Section 8.5 A & D, and 8.6.</p> <p>13.9.1 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>13.9.2 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>13.9.3 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>14.0 Post-Marketing Surveillances FDA Guidelines (Circular No. 2018-012):</p> <p>All Marketing Authorization Holder (MAH) shall establish a PMS system for every product in the market which shall be translated into a product Risk Management Plan (RMP) to be submitted to FDA. The product RMP shall be a requirement for the approval of new applications of new products classified as monitored released (i.e., new chemical entities (NCEs)) and biological products, and shall be based on the latest version of the following guidelines:</p> <ul style="list-style-type: none"> • International Conference on Harmonization (ICH) Harmonized Tripartite Guideline- Pharmacovigilance Planning- E2E • The European Medicines Agency's (EMA) Guideline on Risk Management Systems for Medicinal Products on Human Use; 	<p>FDA Circular No. 2018-012 rescinds Circular NO. 2013-004 and provides new guidance in the conduct of PMS of all drug products, especially for drug products classified as monitored release.</p>

<ul style="list-style-type: none"> • EMA's Guideline on Good Pharmacovigilance Practices (GVP) Module 5- Risk Management Systems; • EMA's Volume 9A of the Rules Governing Medicinal Products for Human Use; and • The U.S Food and Drug Administration Amendment Act of 2007 (FDAAA) and the FDA's Guidance for Industry Format and Content for Risk Evaluation and Mitigation Strategies (REMS), REMS Assessments and Proposed REMS Modifications. <p>Local Phase IV clinical trials for drug products that are classified as monitored release shall be conducted following the FDA-approved protocol, consistent with the guidelines provided under A.O no 67s 1987 as supplemented by A.O No. 2006-0021.</p> <p>Upon submission of the complete and correct requirements, review and approval of the clinical trial protocol and product dossier, the FDA shall grant a Marketing Authorization (MA) distinctly indicating that it is classified under monitored release, which shall valid for three years, unless sooner revoked, but for revision with single extension.</p> <p>Pertinent fees shall adhere to A.O. No. 50 s.2001 Schedule of Fees and Charges for the Corresponding Services Rendered by the FDA.</p>	
<p>15. Honoraria</p> <p>15.1 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> <p>(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.</p> <p>(b) A legitimate need for the services must be clearly identified and documented.</p> <p>(c) The criteria for selecting consultants must be</p>	

<p>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>15.2 Virtual Honoraria</p> <ul style="list-style-type: none"> • For recordings of virtual lectures that are expected for multiple usage to different group of audiences, a company may pay the speaker an additional premium, in addition to the applicable regular in-base lecture rates. • The service agreement should indicate the applicable regular in-base lecture rates plus the additional premium amount. • The additional premium amount should not be more than 100% the applicable regular in-base lecture rate. 	
<p>16.0 Patient Organization, Patients, Patient Support Programs</p> <p>16.1 Definition</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</p>

<p>16.1.1 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>16.1.2 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>16.1.3 Patient Support Programs</p> <p>Programs that involve interaction with patients, including patient education, or programs to ensure patient compliance and adherence</p> <p>16.2 Interactions with Patient Organizations</p> <p>16.2.1 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>16.2.2 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>16.2.3 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>16.2.4 Events for Patient Organizations</p> <p>Companies may provide financial support for patient</p>	<p>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>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>
--	--

<p>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>16.2.5 Communication to Patients</p> <p>Communication with patients should aim at supporting better healthcare and not for purposes of promotion.</p> <p>Careful consideration needs to be made about the appropriateness, language and style of communication. Therapeutic decisions must be made by HCPs only.</p> <p>16.3 Disease awareness programs</p> <p>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.</p> <p>16.3.1 Virtual Disease Awareness Program</p> <ul style="list-style-type: none"> • Disease awareness programs are focused on encouraging patients to seek appropriate treatment and management for their symptoms while not promoting the use of any specific product; thus, only company logos of sponsoring companies will be allowed. • A privacy notice should always be employed in getting consent of participants for the sole purpose of registration and access to virtual platforms. Personal data collected should be protected based on the Privacy Act provisions. <p>16.4 Patient Support Programs</p> <p>Patient Support Programs ("PSPs") should have clear objectives, and should maintain HCP independence</p>	
--	--

<p>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.).</p> <p>16.4.1 Virtual Patient Support Programs</p> <ul style="list-style-type: none"> • A privacy notice should always be employed in getting consent of patients for the sole purpose of registration and access to the virtual applications/ tools. Personal data collected should be protected based on the Privacy Act provisions. Companies are not to access these patient personal data. • Companies are not recommended to participate in telemedicine interactions that should be limited between the HCP and the patient. <p>16.5 Patient Information</p> <p>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. 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>17.0 Communications With The General Public</p> <p>(Refer to Guidelines On Communication Of Prescription Products To The General Public: Appendix 1.)</p> <p>17.1 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>	

17.2 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.

17.3 General media articles may be initiated by manufacturers to announce the holding of a scientific event.

17.4 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.

17.5 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, brand names together with their corresponding generic names may be used.

17.6 Patient education should encourage patients to seek further information or explanation from the appropriate healthcare professional.

17.7 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.

17.8 The educational material must contain a statement directing the patient to seek further information from his or her healthcare professional.

17.9 Patient Aids

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

<p>not make comparisons or include promotional claims. To ensure compliance, patient aids must be administered by the appropriate healthcare professional.</p> <p>17.10 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>18.0 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. 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:</p> <ol style="list-style-type: none"> 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. 	<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>

<p>6.The discount feature or scheme cannot be tied to sales promotion, raffles or promise of reward that may encourage self-prescription.</p> <p>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.</p>	
<p>19.0 Administration of the Code</p> <p>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.</p> <p>Complaints Handling Procedure</p> <p>19.1 Intercompany Discussions First</p> <p>Member companies are encouraged to settle matters among themselves before elevating the issue to the PHAP Ethics Committee.</p> <p>19.2 Submission of Complaints</p> <p>Complaints must be in writing or by e mail and must include:</p> <p>Complainant details:</p> <ul style="list-style-type: none"> •The true identity of the complainant with a full mailing address (including fax number and email, if possible) for correspondence. <p>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.</p>	

<p>•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).</p> <p>•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> <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>19.3 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>	

Finally, if a complaint cannot be validated, it shall not be processed and the complainant must be notified accordingly.

19.4 Notice

Within five (5) working days from receipt by PHAP of the valid complaint, a copy, including any supporting evidence (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".

19.5 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.

19.6 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.

19.7 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

<p>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> <p>19.7.1 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>19.8 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>19.9 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 and company name will 	

<p>be published on the PHAP website.</p> <ul style="list-style-type: none">• 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>20.0 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>21.0 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>22.0 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>	

Table 1: 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 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 **and outside 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. ^[1]
- It is acceptable for virtual lectures to have an **additional exact amount or no more than 100% original in-base amount** of lecture fee with the expectation for lecture to be used repeatedly as needed.

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	



PHARMACEUTICAL & HEALTHCARE
ASSOCIATION OF THE PHILIPPINES



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.

September 2020

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.

Frequently Asked Questions on PHAP Code Virtual Engagement Guidelines

Introduction

This FAQ document is developed to further guide PHAP Member companies in interpreting the PHAP Code of Practice Virtual Engagement Guidelines. Member companies should adhere to the requirements established by applicable laws, regulations, PHAP Code of practice and internal company guidelines. In the event of a conflict between the provisions of the applicable laws, regulations, and codes, the more restrictive of the conflicting provisions should apply.

The Scope of the PHAP Code of Practice Virtual Engagement Guidelines

1.Does the guidance also relate to hybrid meetings?

This guidance is specifically released for purely virtual meetings. Hybrid meetings should follow the principles of face-to-face meetings. If there is a virtual element to the congress, the guidance principles should be adhered to. Please note that for Hybrid meetings, the 'host-country' code (as per face-to-face congress) and label is applicable. Therefore, companies can apply them in the development of materials or communications. (IFPMA, EFPIA, PhRMA Joint Guidance Q&A document)

2. What are obligations with respect to ensuring privacy within the medical society is maintained? A number of medical societies are selling their detailed delegate list to sponsors. What happens if companies sponsor HCPs and register the HCPs on their behalf?

The obligations around privacy do not differ between virtual meetings and face-to-face meetings. Companies need to ensure that when registering HCPs themselves, they counsel HCPs of the terms and conditions. Companies also have an obligation to check that information around privacy will be included on the congress website so that HCPs are aware of the privacy implications upon entering the site. It is the medical society's ultimate responsibility that they are adhering to the privacy obligations of the country they are operating in and that they are clear to the HCP as to what they are doing with their personal information.

(IFPMA, EFPIA, PhRMA Joint Guidance Q&A document)

3. Are company organized virtual meetings covered by the PHAP Code of Practice Virtual Engagement Guidelines?

Data privacy principles provided by the National Privacy Act of 2012, as reiterated in the PHAP Code of Practice Virtual Engagement Guidelines should always be applied to company-organized virtual meetings.

The frequency and limit to the number of participants provided to virtual CMEs are not applicable to company organized meetings. Companies should refer to their internal processes for organizing such virtual meetings.

Guidance on provision of meals to participants is applicable to company organized events. Sending of meals to individual doctors especially in their residence is prohibited.

The product logos or names are allowed for company events like product launches.

4. What are company organized meetings/ events?

Company initiated events are activities independently organized by companies, either on its own or through a third party on behalf of the Company that provide product, disease awareness, or other product-related information to HCPs for promotion or non-promotional reasons. The Company has control over the agenda, location, HCP selection, speakers, or management of the meeting and event.

The following are examples of company organized events.

- o Product presentation
- o Round table discussion
- o Focus Group Discussion
- o Product Launch
- o Advisory board
- o Symposium
- o Clinical trial meetings
- o Investigator meetings
- o Tactical activities

5. What type of information can be shared via SMS, WhatsApp, Viber, etc.?

It depends on the consent obtained by the company and the terms and conditions of the platforms.

PHAP Code provisions on promotional materials shall apply.

Virtual Exhibit Booths

6. What are Virtual Exhibit Booths?

Similar to regular exhibit booths at scientific conferences, the virtual booths are spaces/ ads or links where companies share information about their products and services, showcase their latest innovations.

7. The PHAP Code Guidelines specify “Add virtual booth system including specific time slots to enable access of participants only during breaks.”

Does this mean that companies can present/show product logos after or before the CME?
Or this is solely for booth sponsorship?

Presentation of products/ logos are allowed only for virtual booth spaces. The main lecture session should be purely for Continuing Medical Education (CME). There should be no promotions of any kind. Product presentations should have a specific time slot and not as a part of CME program.

8. How should the virtual platform separate investigational and disease inquiries from marketed product inquiries?

A minimum disclaimer should be applied. Where possible, you can ask the HCP to categorize the query (e.g. through selection of a dropdown menu) prior to responding to the question. Please note: this is no different from face-to-face meetings.

(IFPMA, EFPIA, PhRMA Joint Guidance Q&A document)

9. Can brands be mentioned before each session begins if there is no segregation for promo like a virtual booth area?

It is important to clearly indicate to the delegate what information is promotional and what is non-promotional. A medical/scientific session should not be associated with promotion of any product. When discussing brand information, you must follow the relevant code provisions for promotion.

(IFPMA, EFPIA, PhRMA Joint Guidance Q&A document)

10. Can we use brand colors in virtual scientific/promotional/’social area’?

The use of color branding should follow the relevant country code’s provision for promotional activities. For non-promotional sites/areas, branding colors should not be used to avoid the perceived promotion.

(IFPMA, EFPIA, PhRMA Joint Guidance Q&A document)

11. If an international medical society holds a congress with many delegates being from outside of host country, would it be acceptable to share information about a product indication which is not approved in the host country, but is approved in, for example, North America and Japan?

It is critical that the company clearly indicates which label has been used for the development of promotional material and has a disclaimer indicating that registration conditions differ internationally and that HCPs should refer to prescribing information from their country of practice as information may be different for each country.

(IFPMA, EFPIA, PhRMA Joint Guidance Q&A document)

12. Is it sufficient to have delegate click a check-box confirming he/she is an HCP, or should there be additional validation (name, country, professional affiliation, etc.)?

When a delegate enters a company area where promotional information is provided, there should be a clear disclaimer of what is presented. It is sufficient to have the HCP indicate through a check-box or validation mechanism confirming their status as a HCP and they accept the shared responsibility that they will only access what they are supposed to see.

Conduct of Virtual Meetings

13. Why are we limiting provision of meals to a minimum of 5 HCP participants gathered in one venue.

Meals are only provided as incidental to the meeting. In order to be construed that the meals is not the main purpose of the virtual CME or meetings, a minimum of 5 participants is the approved recommendation from the PHAP Governance and Compliance subcommittee members and PHAP Board members. Sending of meals to individual HCPs especially in their residence can be construed as provision of gift.

14. What if a webinar meeting will run simultaneously nationwide where HCP's are in different venues or location, should we still follow minimum limits in providing meals in each venue?

We can provide meals to a gathering of 5 in different appropriate locations/ meeting venues.

Internal company controls should be in place.

15. Why are we limiting sponsorship to twice a year limit per participant for international/ regional CMEs?

This recommendation by the PHAP Governance and Compliance subcommittee is based on the goal to help give equitable opportunities to all HCPs.

16. We are allowed to sponsor doctors to foreign virtual congresses twice each year. If face-to-face international congress will already be allowed, can we still sponsor a doctor to this face-to-face congress once each year on top of the 2 virtual foreign congresses?

No.

17. How about 1 virtual and 1 face-to-face sponsorship?

In the event that face-to-face meetings resume, HCPs can only be sponsored either 1 face-to-face or 2 virtual sponsorships per year.

September 2020

18. Does DOH AO 2015- 0053 Implementing Guidelines on the Promotion and Marketing of Prescription Pharmaceutical Products and Medical Device (also known as MCP AO) limit of 20 participants still apply in virtual international CME sponsorships?

The limit does not apply to virtual CME sponsorships. The AO guidelines on limit of 20 HCPS was specifically for CME sponsorships involving international travel. For face-to-face sponsorships, the PHAP Code limits sponsorship to 7 (International/ Regional) and 12 (Asia).

Virtual Lectures Honoraria

19. In relation to Virtual Honoraria, if the role of the HCP consultant is moderator only, and the virtual session of the moderator was recorded for post-viewing/video highlights for subsequent virtual events/required by the medical society, do we consider paying additional honoraria for the moderator recording?

Provision on additional premium is not applicable to moderators.

20. Does Virtual Honoraria also cover recording/reuse of “live” Q&As? We noted some events (even third party conventions) where there is a live Q&A, and they record the session with this Q&A segment, and make it accessible/available for a certain period in the website. Should this be paid separately to the speaker (on top of honoraria for speaker + recording/reuse of lecture + live Q&A) or would it already be covered by the recording/reuse fee?

There should be no additional premium for Q&As.

21. Can the companies sponsor the virtual platform subscription for Medical Societies?

No.

22. In relation to Virtual Patient Support Programs which states “Companies are not recommended to participate in telemedicine interactions that should be limited between the HCP and the patient,” if the Company were to provide a telemedicine platform through a program but not participate in the interactions between HCP and patient, will this be allowed?

This provision refers to the MD-patient virtual consultations only where the companies are not allowed to get involved (e.g. promotional products appearing on screen, drop-down list of products in the Rx generation page).

23. Can companies sponsor telemedicine apps?

No.



PHARMACEUTICAL & HEALTHCARE
ASSOCIATION OF THE PHILIPPINES

PHAP Members



PHAP Members

1. Abbott Laboratories
2. Astellas Pharma Philippines, Inc.
3. AstraZeneca Pharmaceuticals
4. Ayala Healthcare
5. Bayer Philippines
6. Blue Sky Pharma
7. Boehringer Ingelheim
8. Calmoseptine
9. Champion Biotech
10. Ferring Pharmaceuticals
11. Galderma
12. GlaxoSmithKline Philippines
13. Glenmark Philippines, Inc.
14. Hi-Eisai Pharmaceutical
15. IQVIA
16. Johnson and Johnson
17. Merck, Inc.
18. Merck Sharp and Dohme
19. Mercury Drug Corporation
20. Metro Drug, Inc.
21. Mundipharma Distribution GmbH
22. Novartis Healthcare
23. Novo Nordisk Pharmaceuticals
24. Otsuka (Philippines) Pharmaceuticals
25. Panpharma-Meinz Healthcare and Pharmaceuticals Inc.
26. Pfizer, Inc.
27. PhilUSA Corporation
28. PharmAsia-Cuvest
29. Qualimed
30. Roche (Philippines), Inc.
31. Rudolf Lietz
32. Sanofi-aventis
33. Swiss Pharma
34. Taisho Pharmaceutical
35. Takeda Healthcare Philippines Inc.
36. TGP Pharma Inc.
37. Vizcarra Pharmaceutical
38. Watsons Personal Care Store
39. Zuellig Pharma Corp

*Members list updated as of reprint in February 2018.

September 2020
