

1	REVISED CODE	EXPLANATORY NOTES
	<p style="text-align: center;">CODE OF PHARMACEUTICAL MARKETING PRACTICES</p> <p>PREAMBLE</p> <p>The PHAP Code of Pharmaceutical Marketing Practices (hereinafter referred to as the “Code”) adopts in full the IFPMA code and incorporates local requirements and practices in relation to registration, labeling and scientific claims approved by the drug regulatory authority.</p> <p>The PHAP Code of Marketing Practices also acknowledges the role of relevant codes developed by the World Medical Association and World Health Organization.</p> <p>PHAP and its members are committed to educational and promotional efforts that benefit patients and promotional programs and collaborations that enhance the practice of medicine. PHAP also seeks to preserve the independence of the decisions taken by healthcare professionals in prescribing medicines to patients. The ethical promotion of prescription medicines is vital to the pharmaceutical industry’s mission of helping patients by researching, developing and marketing new medicines. Ethical promotion helps to ensure that healthcare professionals have access to information they need, that patients have access to the medicines they need and that medicines are prescribed and used in a manner that provides the maximum healthcare benefit to patients.</p> <p>The pharmaceutical industry has an obligation and responsibility to provide accurate information and education about its products to healthcare professionals in order to establish a clear understanding of the appropriate use of prescription medicines.</p> <p>Industry relationships with healthcare professionals must support, and be consistent with, the professional responsibilities healthcare professionals have towards their patients. Pharmaceutical companies must maintain high ethical standards when conducting promotional activities and comply with applicable legal, regulatory and professional requirements. Through the promotion of this Code, PHAP seeks to ensure that ethical promotional practices are established worldwide.</p>	

The PHAP Code covers not only member companies of PHAP but also local subsidiaries of IFPMA member companies.

1.0 CODE OF PHARMACEUTICAL MARKETING PRACTICES

1.1 Scope of Coverage

Promotion and advertisement of pharmaceutical products directed to healthcare professionals are deemed to fall within the scope of the Code.

“pharmaceutical product” means all pharmaceutical or biological products (irrespective of patent status and/or whether they are branded or not) which are intended to be used on the prescription of, or under the supervision of, a healthcare professional, and which are intended for use in the prevention, diagnosis and treatment of disease in humans, or to affect the structure or any function of the human body.

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

“healthcare professional” means any member of the medical, dental, pharmacy or nursing professions or any other person who in the course of his or her professional activities may prescribe, recommend, purchase, supply, or administer a pharmaceutical product.

1.2 Interpretation of the Code

All matters of interpretation of any section of the PHAP Code, must be consistent with the **Preamble**.

1.3 Responsibility for Implementation

The General Manager/President/Managing Director is responsible for the proper implementation of the Code and its implementing guidelines. They shall ensure that all company employees and the company's external advertising and/or public relations agencies, are conversant with the PHAP Code. Press releases fall under this provision. (note: refer to GUIDELINES ON COMMUNICATION OF PRESCRIPTION PRODUCTS TO THE GENERAL PUBLIC – Appendix 1

1.4 Exclusions of the Code

This Code does not seek to regulate the following activities:

*Promotion/advertising/detailing of over- the-counter products to the trade and public BUT TO HEALTHCARE PROFESSIONALS, PROVISIONS OF THIS CODE APPLY.

* Pricing or other trade terms for the supply of pharmaceuticals products.

2.0 MEDICAL INFORMATION AND CLAIMS

2.1 Responsibility

It is the responsibility of companies, their employees and their medical/technical advisers to ensure that the content of all promotional and medical claims is balanced, accurate, correct and fully supported by the Product Information, literature or "Data on File" or appropriate industry source, where these do not conflict with the Product Information.

Activities of company representatives and company advertising and PR agencies shall comply with the PHAP Code at all times.

2.2 Provision of Additional Information

The member company will provide additional accurate and relevant information about products being marketed to healthcare professionals upon written request.

All data cited in promotional materials in support of a claim must be provided within 10 working days upon request. Substantiating information must not rely solely on “data on file”; the company must have them available upon request.

2.2.1.Provision of Substantiating Data

In addition to the information supplied or generally available, a company will, upon reasonable request, provide healthcare professionals with additional accurate and relevant information about products which it markets, including company information.

Data in support of a claim, including “data on file” or “in press” MUST BE MADE AVAILABLE without delay upon reasonable request even though the material is not generally available to the medical community.

2.2.2 Level of Substantiating Data

Any information used to support a medical or promotional claim must include sufficient detail and be of adequate quality to allow evaluation of the validity of results and hence the claim.

detail and be of adequate quality to allow evaluation of the validity of results and hence the claim.

Such substantiating information must not rely solely on “data on file” but must be supported by a published article.

<p>2.3 Accurate Scientific Claims</p> <p>All information, claims and graphical representations provided to healthcare professionals and members of the general public must be current, accurate , balanced and must not be misleading either directly, by implication, or by omission. Every effort must be made to avoid ambiguity.</p> <p>Claims must be referenced where there is a possibility that a reader may be misled if the source of the reference is not disclosed.</p> <p>2.2.1 Unapproved products and indications</p> <p>Products that have not been approved for registration by the Bureau of Food and Drug cannot be promoted. However, samples of unapproved products may be displayed and educational material made available at International Congresses and Regional Congresses in accordance with Section 9. This restriction also applies to unapproved indications for registered products.</p>	<p>2.1.1</p> <p>This responsibility relates not only to the product being promoted, but to any information given or claims made about other product or disease states or conditions. It also applied to tag lines and their ability to be substantiated.</p> <p>It is fundamental that any claim made must not be inconsistent with the Philippines. Product information document, irrespective of the source on which the claim is based.</p> <p>2.2.1.1</p> <ul style="list-style-type: none"> (a) All data to substantiate claims must be easily retrievable so that they could be supplied on request within 10 working days. (b) Evaluated data contained in an application for marketing may be used to substantiate claims. Such data must be made available when requested to substantiate a claim. A statement that the data are “Confidential” will not be accepted.
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	<p>(c) If the information on which a claim is based may not be released, e.g. an “in press” article which is subject to confidentiality provisions then that information MAY NOT BE USED TO SUBSTANTIATE A CLAIM for the purposes of satisfying this section. Papers cited as “in press” must have been accepted for publication and be available as a final approved manuscript or in proof form. Papers submitted for publication and not yet accepted by a journal may be identified only as “unpublished data”, “personal communication”, “unrefereed data” or similar terms.</p> <p>(d) Data relating the cost effectiveness of a product may be used to substantiate promotional claims, however these data must conform with Sections 2.1.2.2., 2.3, 2.5 and 2.7 of this Code.</p>
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		<p>In determining whether sufficient evidence is available to support a claim, companies should have regards to issues such as, but not limited to, the study design, the number of patients, the location of any trial or study, its primary purposes and end points, the results, the reputation and qualifications of the people involved in the study or trial, its consistency in the current body of evidence and where (e.g. peer reviewed journal or professional journal) or if it has been published.</p> <p>For example, to satisfy the requirements of this section the evidence to support any major claim that will have a significant impact on the prescribing of a product, must be unequivocal and of the highest quality. It should not rely upon evidence from sources such as poster presentations or abstracts that do not provide sufficient information to assess the veracity of the claim. Used appropriately which these information sources may be used to support lesser or minor claims.</p>
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2.4 Good Taste

All promotional and educational material (including graphics and other visual representations) must conform to generally accepted standards of good taste and recognize the professional standing of the recipients.

These materials must not contain anything which would likely cause serious or widespread offense against prevailing community standards.

2.5 Unqualified Superlatives

Unqualified superlatives must not be used. All claims must not imply that a product or an active ingredient is “unique”* or has some special merit, quality or property, unless the claim(s) can be substantiated. The word “safe” for example, must not be used without qualification.

2.6 New Products

The word “new” must not be used to describe any product, presentation, or therapeutic indication which has been available and generally promoted for more than 12 months in the Philippines.

2.3.1

The majority of breaches of the Code found concern this section. The following are examples of situations where material may breach the Code. This list is not all inclusive and is based on the experience of the Ethics Committee.

- (a) Literature references or quotations derived from a study or studies and citations of individual opinions which are significantly more favourable or unfavourable than has been demonstrated either within the study, or more likely from the body of experience. It is unreasonable to cite the results of an excessively favourable (or excessively unfavourable to a comparative product) study in a manner which misleadingly suggests that those results are typical.
- (b) Information or conclusions from a study that is clearly inadequate in design, scope or conduct to furnish support for such information and conclusions.

2.7 Comparative Statements

2.7.1 Comparison of products must not be disparaging, but must be factual, fair and capable of substantiation and referenced to its source. Care must be taken to ensure that it does not mislead by distortion, by undue emphasis or any other way. Clinical terminology should be used to describe improved benefits rather than mere claims that a product is better, stronger, more widely prescribed, etc.

“Data on file” when used to substantiate comparative statements must comply with the requirements of Section 2.2.

2.8 Imitation

Promotional information should not imitate the devices, copy, slogans or general layout adopted by other manufacturers in a way that is likely to mislead or confuse.

2.9 Medical Ethics

Healthcare professionals’ names or photographs must not be used in any way that is contrary to professional ethics.

2.10 Distinction of Promotional Material

Promotional material and advertisement must identified as such.

- (c) Citation of data previously valid but made obsolete or false by the evaluation of new data.
- (d) Suggestions or representations of uses, dosages, indications or any other aspect of the Product Information not approved by the Bureau of Food and Drug.
- (e) Shortening an approved indication (e.g. in a by-line) so as to remove a qualification or limitation to the indication.

- (f) Use of animal or laboratory data as sole evidence to support a promotional claim. It should be noted that if animal or laboratory data are used a prominent statement identifying this type of data and acknowledging that such data does not necessarily predict clinical effects must be made on the same page and within reasonable proximity to the data in a manner that is not obscured by other material.

3.0 PRODUCT INFORMATION

The PHAP is committed to the rational use of medicines and central to this goal is the provision of relevant information to healthcare professional. Such information should include knowledge gained during the research and development process of medicines as well as from their clinical use. Healthcare professionals in the Philippines should have access to similar data as those being communicated in developed countries.

3.1 Full Disclosure Product Information

A full disclosure Product Information must accompany all promotional materials for a period of at least 12 months from the date of product launch.

Exceptions to full disclosure rule are items and materials that serve only as reminders of the product's existence without making promotional claims. This full disclosure rule shall apply also to reformulated products as approved by BFAD. Where the material only indicates the brand name, generic name and preparation, no full disclosure of product information shall be required.

The Product Information should include:

- 3.1.1 The Brand name; the generic name (INN) of each active substance;
- 3.1.2 Pharmacological data - brief description of pharmacologic effects and mechanism of action;
- 3.1.3 Clinical information including: indications, dosage regimen and relevant pharmacokinetic data, contra-indications, precautions and warnings, adverse effects, drug interactions, overdosage precautions.
- 3.1.4 Pharmaceutical information: dosage forms, strength of dosage forms, storage conditions and description of the product and the name and address of manufacturer(s) and importer(s).

(g) Presentation of information in such a manner e.g. type size and layout, which, to the casual reader could produce an incorrect perspective. The type size used for qualifying statements must not be less than 2mm. The qualifying statement must not be included with other reference material but must be situated on the same page as the original statement. The original statement and the qualifying statement must be linked by use of a readily identifiable asterisk or a similar symbol.

(h) Statements made about a competitive product, particularly negative statements, not balanced with corresponding information about the product being promoted.

(i) Shortening the title graphical representations reproduced from literature which alters the original author's meaning.

3.2 Abridged Disclosure Product Information

- 3.2.1 Brand name, the generic name (INN) of each active substance
- 3.2.2 Approved indications for use;
- 3.2.3 Contra-indications;
- 3.2.4 Precautions for use;
- 3.2.5 Adverse effects and drug interactions;
- 3.2.6 Available dosage forms; dosage regiments,
- 3.2.7 Routes of administration, and
- 3.2.8 Reference to special groups of patients.

4.0 ALL PROMOTIONAL/ EDUCATIONAL MATERIAL

4.1 Advertising

in Healthcare Professional Journals

An advertisement must contain at least the following:

- 4.1.1 Brand name of the product:
- 4.1.2 Generic name of the active substances;
- 4.1.3 Name and address of the supplier
- 4.1.4 Full disclosure Product Information is mandatory to advertisements appearing within 12 months after product launch and abridged Product Information may be used 12 months after product launch.
- 4.1.5 The phrase "Please review Product Information before prescribing" should be clearly printed.
- 4.1.6 Date of production of the advertisement

- (j) Use of overseas Product Information to support a claim where that information is inconsistent with the Philippines Approved Product Information.
- (k) Literal or implied claims that a parameter, contra indication, precautionary statement, adverse reaction or limitation on a claim in the Product Information, is not cause for concern.
- (l) Lack of substantiation of claims not of a medical or scientific nature. It includes information or claims relating to marketing factors such as pricing and market share. Care should be taken when extrapolating prescribing from sales data.

2.3.1.1.1

Where a company has been formally advised by the Bureau of Food and Drugs that a product has been approved and its Product Information has been finalised, it is considered approved for registration for the purpose of this Code.

<p>If the advertisement makes no promotional claims, the following minimum information should be supplied:</p> <p>4.1.7 Brand name, 4.1.8 Generic name of active substances, 4.1.9 Name and address of the supplier, and 4.1.10 The statement “Additional information is available upon request”.</p> <p>4.2 MIMS Advertising The requirements for journal advertising also apply to advertisements in MIMS and other similar references.</p> <p>4.3 Company Commissioned Articles – (note refer to – Guidelines on Communication of prescription products to the General Public – Appendix 1</p> <p>4.3.1 Company commissioned articles must be identified as such in a type size not less than 2 mm.</p> <p>4.3.2 The PHAP member, which is responsible for the insertion of the Company Commissioned Article, must be clearly identified at either the top or the bottom of the Company Commissioned Article, in a type size of not less than 2 mm.</p> <p>4.3.3 Company Commissioned Articles must conform to all relevant provisions of Section 1 of this Code.</p>	<p>2.5.1</p> <p>Although in some circumstances “unique” may be used to describe some clearly defined special feature of a medicine, in many instances it may be taken as implying a general superiority. In such instances this is unacceptable unless the claim can be supported in every respect.</p> <p>Use of the definite article to imply a special merit, quality or property for a medicine is unacceptable under this clause if it cannot be substantiated. For example, a claim that a product is “The analgesic” implies that it is in effect the best, and might not be acceptable under this clause.</p> <p>2.7.1</p> <p>Pharmaceutical advertising commonly contains comparisons with other products and such comparisons are usually made to show advantage of the advertised product over its competitor(s). Provided that such comparisons with other products are factual, fair and can be substantiated, they are acceptable under the Code.</p>
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<p>4.3.4 Commissioned Articles shall also conform to the requirements of Section 3.1.1 of the Code of Conduct.</p> <p>4.4 Short Advertisement - Reference Manuals Short advertisements in reference manuals shall correspond to the requirements of Section 3.1.3 of the Code.</p> <p>4.5 Materials for use by Medical Representatives</p> <p>4.5.1 Covered in this section are detail aids, leaflets, and posters containing promotional claims intended for distribution to healthcare professionals.</p> <p>4.5.2 The rule is all promotional claims must be accompanied by Product Information.</p> <p>4.5.3 Printed promotional material and audiovisual material must contain the following information: brand name of the product; generic name of the active ingredients; name and address of the supplier and full or abridged Product Information.</p>	<p>The intention of this clause is to prohibit unfair and unjustified comparisons with the products or activities of a competitor.</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 does not reflect the general literature, as those documents are based on different databases and are not directly comparable. This applies to Philippines as well as overseas Product Information documents.</p> <p>Claims of comparative efficacy or safety should be substantiated with respect to all aspects of efficacy or safety. Where a comparative claim relates to a specific parameter, any claims must be clearly identified as pertaining to that parameter.</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> <ul style="list-style-type: none"> • Lack of significance must be stated explicitly; its insufficient to state the p value; and
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4.5. 4 Promotional Give-aways

Promotional give-away items like pens, notepads and mugs where no promotional claims are made do not require Product Information. However, these items should not be of a nature of economic value (valued less than PhP1,000), which would bring discredit upon the industry or the recipient, items of higher cost may be donated to institutions (such as medical societies, professional organizations, hospital departments, etc.) but never to individuals.

4.5.5 If promotional claims are made, these items must be accompanied by a document containing the required information.

4.5.6 Medical literature and reprints must be consistent with the Product Information.

4.5.7 Quotations from medical literature, conferences or from personal communications must accurately reflect the meaning of the author and the significance of the study.

4.6 Electronic Promo Materials including audiovisuals such as PowerPoint presentations, CD's, DVD's, etc.

4.6.1 All previously discussed rules apply to these materials. In case of pharmaceutical product related websites, the following guidelines should be observed:

- The data must not be used to generalise or to indicate superiority or inferiority.

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 of the original claim in a manner that is not obscured by other material 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.

2.9

Wherever a healthcare professional's name is specified in any kind of promotional material, other than by citation of a published reference, the Company should ensure that the individual specified is aware of and provides written approval for the use of his/her name in the context of the entire promotional material. For example, if a doctor agrees to introduce an educational video,

<ul style="list-style-type: none"> • the identity of the pharmaceutical company and of the intended audience should be readily apparent; • the presentation (content, links, etc.) should be appropriate and clear to the intended audience; • country-specific information should comply with local laws and regulations. <p>4.6.2 Where an individual product is being promoted, the appropriate Product Information must be offered to an individual reviewing the promotional material, readily accessible via the computer-based material or offered to an audience in a group situation on completion of the presentation.</p> <p>4.6.3 Where the Product Information is included in interactive data system, instructions for accessing it must be clearly displayed.</p> <p>4.6.4 Where promotional or medical claims are included in the computer-based promotional material, details of the substantiating references must be readily accessible via the computer-based promotional material.</p> <p>4.6.5 The type size and graphics used in all promotional material must allow easy and clear legibility.</p> <p>4.6.6 Where an audiovisual item is demonstrated, the Product Information document must be given to the individual reviewing the promotional material, or offered to the audience in a group situation on completion of the presentation.</p> <p>4.7 Brand Name Reminders</p> <p>4.7.1 Brand name reminders must include the following information:</p> <ul style="list-style-type: none"> (a) the brand & generic name of the product; (b) Other BFAD approved name(s) of the active ingredient(s), wherever applicable; (c) Where applicable, the annotation “See Boxed Warning” drawing attention to the boxed warning in the Product Information. 	<p>they should be fully ware of the final content of that video, such as a situation would imply endorsement.</p> <p>The company should also obtain written approval from the individual if his/her name is used in subsequent promotion material.</p> <p>2.10</p> <p>Advertisement in a journal should not be designed to resemble editorial matter unless clearly identified as an advertisement. See also Section 4.3</p>
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4.7.2 Brand Name Reminders are not to contain any promotional claims/and or statements.

4.8 Lay Media Advertising

Lay media advertising shall not be allowed for prescription products. Provision of Section 16 and Appendix 1 - Guidelines on Communication Prescription Products to the General Public shall apply.

5.0 MAILINGS, FAXES, EMAILS, TEXT MESSAGES

5.1 These communications must comply with all relevant provisions of the Code.

5.2 These communications should only be sent 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 lists must be complied with promptly and no name restored except at specific request or with written permission.

5.3 Mailing lists should be kept up-to-date.

5.4 Exposed mailings including postcards, envelopes or wrappers must not carry matter which might be regarded as advertising to the general public or which could be considered unsuitable for public view.

5.5 Document Transfer Media
Unsolicited electronic transmissions or replicas thereof, must not be used for promotional purposes.

6.0 COMPETITIONS AND RAFFLES

Competitions must fulfill all of the following criteria:

6.1 Raffles and competitions are only permitted during official conventions organized by the PMA or its affiliates. It should not conflict with any of the official convention activities.

6.2 Competitions must be based on medical knowledge or on the acquisition of it. The contest may involve answering simple questions or the preparation of elaborate reports or presentations, hence, the prizes must be proportionate to the complexity of the contest.

6.3 The prizes must be relevant and specific to the practice of medicine. Prizes may include stethoscopes and other medical equipment.

6.4 Individual prizes offered are to be of low monetary value (less than P1000) or be an item of educational material.

6.5 Entry into a competition must not be dependent upon prescribing, ordering or recommending of a product and no such condition shall be made or implied.

6.6 The conduct of competitions shall comply in all respects with relevant government regulations.

7.0 THE USE OF THE INTERNET FOR PHARMACEUTICAL INFORMATION

PHAP supports the right of its Members to use the Internet as a means of providing accurate and scientifically reliable information on medicines in a responsible manner for the benefit of both patients and healthcare professionals.

Local websites have to follow all rules of the Code on promotion and advertising. For example, the promotion/advertising of products covered by the Code to the general public via the internet, would breach Section 16.0 of the Code.

The following provisions are applicable to information generated for use via Philippine Internet sites.

7.1 Healthcare professionals should be provided with access codes for information not be consumed by the general public.

7.2 Should a Member company link its web site to PHAP's website, this does not constitute PHAP endorsement of the company's site nor its content.

8.0 MEDICAL REPRESENTATIVES

8.1 Medical 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.

8.2 Members have a responsibility to maintain high standards of ongoing training for representatives like MRAP (Medical Representative Accreditation Program).

8.3 Medical representatives should, at all times, maintain a high standard of ethical conduct in the discharge of duties.

8.4 Medical representatives must ensure that calls do not inconvenience or hinder the healthcare professionals' performance of his or her duties. Medical representatives should conform with institutional regulations governing their calls.

8.5 Whenever a promotional claim is made, the medical representative must provide the Product Information, as approved for the Philippines.

9.0 PRODUCT SAMPLES

9.1 In accordance with BFAD regulations, free samples of a pharmaceutical product may be supplied to healthcare professionals, and only with their consent, in order to enhance patient care and/or to gain clinical experience. Samples should not be sold or otherwise misused by medical representatives and employees. (explanatory note on misuse)

9.2 The quantity of samples given should be appropriate for:

9.2.1 healthcare professionals to initiate therapy; and/or

9.2.2 gain clinical experience with the product;

9.3 Product samples may be given for humanitarian reasons but dispensing must be under the supervision of a qualified healthcare professional.

9.4 Product samples must be accompanied by product inserts.

9.5 Product samples must comply with the labeling requirements of BFAD and must be clearly marked "Physician's Sample - Not For Sale".

10.0 EXHIBIT BOOTHS

10.1 The main objective of congresses and symposia is medical education. Hospitality attendant to such events is always secondary.

10.2 Exhibit booths must be directed only to healthcare professionals. The display must clearly identify the exhibitor and must comply with all the requirements of the organizer and the relevant provisions of this Code.

10.3 Product samples may be given to healthcare professionals attending congresses or symposiums but these samples must always be accompanied by Product Information.

10.4 Contests, raffles and other similar activities conducted in the booths are allowed provided prizes are limited to stethoscopes, medical books, medical journals and tokens described in Section 4.5.4. Such contests, raffles and similar activities may not be conducted at times which conflict with any existing scientific event or draw symposium participants away from scientific events and satellite symposia.

10.5 Video presentations must be scientific or related to the products promoted.

11.0 Continuing Medical Education

Symposia, congresses and the like are important for the dissemination of knowledge and experience. Scientific objectives should be the principal focus in arranging meetings. Entertainment or other hospitality shall be consistent with CME objectives.

11.1 Conventions, Symposia, Scientific Programs and Post Graduate Courses.

This section covers participation in and sponsorship of continuing medical education and other medical activities organized by various medical specialty societies or by pharmaceutical companies, whether expenses are paid for by the local Pharma company or its affiliate or HQ, held locally or outside the country.

No company may organize or sponsor an Event for healthcare professionals (including sponsoring individuals to attend such Events as described in 11.5.1 and 11.9.1) that takes place outside of their home country unless it is appropriate and justified to do so from the logistical or security point of view. International scientific congresses and symposia that derive participants from many countries are therefore justified and permitted. Travel should be by Economy Class.

11.2 The scientific agenda must be the primary basis for the company's sponsorship of or participation in the event and any support to individual doctors should not be conditional upon any obligation to prescribe or promote any medicinal product.

<p>11.3 Multi-Companies/Products In instances when an umbrella organization has two or more companies handling different compounds to be represented in the same congress, the organization may be allowed to sponsor up to seven (7) doctors per company or up to twelve (12) for regional scientific meetings, subject to the approval of the Ethics Committee. Such organization must obtain clearance from the Committee at least two (2) months prior to the event.</p> <p>11.4 While pharmaceutical companies may support continuing medical education, they should not conduct tours, socials, games, contests, sports and other activities that draw participants away from the official CME activities. Activities before and after the CME program are considered acceptable if in line with the PHAP Code of Ethics guidelines.</p> <p>Sponsorship of the healthcare professional must be limited to travel to and from the venue and accommodation for the period of the scientific event with a maximum of an additional two days only. Sponsorship of side trips of the healthcare professional is unacceptable.</p> <p>11.5 Pharmaceutical companies are strongly encouraged to observe reasonable restraint in expenditures related to CME. Member companies may sponsor healthcare professionals to attend CME events. Invitations should be extended only to healthcare professionals in the professional's area of activity/interest. Furthermore, such sponsorships must be in accordance with the following requirements:</p> <p>11.5.1</p> <p>A pharmaceutical company is allowed to sponsor only healthcare professionals' accommodations, meals, transportation and scientific program registration for recognized medical societies' scientific meetings. Registration fee should be paid by healthcare professionals in order to encourage attendance to scientific sessions. Cash assistance or check voucher is not acceptable under any circumstances. Neither is payment of expenses for spouses or family.</p>	
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11.5.2

In addition to the Philippines, the venue of CME events may be the Americas, Europe, Australia, Japan, or the ASEAN countries, Hong Kong, Taiwan, China, Korea, and India.

11.5.3 For overseas venues, pharmaceutical companies may sponsor seven (7) healthcare professionals for the Americas, Europe, Australia and Japan. For ASEAN countries, Hongkong, Taiwan, India, Korea, companies may sponsor up to twelve(12) healthcare professionals.

11.5.4 For CME events in the Philippines, pharmaceutical companies may sponsor any number of healthcare professionals, provided the professionals will pay the registration fee. The scientific program must constitute a minimum of 66% of the time in the given location and/or locations before or after the scientific agenda, outside of reasonable travel time and must be held in business accommodation locations, and not primarily resort locations.

11.6 No honoraria or compensation will be given to the healthcare professional for attending the convention, symposium or CME event. This provision does not apply to healthcare professionals sponsored as speakers in a CME event.

11.7 Limits of Hospitality

Hospitality should be limited to refreshments and/or meals incidental to the main purpose of the event. Hospitality should only be provided if it :

- Is for participants of the event and not their guests;
- Is moderate and reasonable as judged by local standards;
- does not use star talent to attract participants to the meeting;
- Is held in business venues and not in venues such as discos, nightclubs, resorts or other places where refreshments and/or meals are incidentally available.

11.8 Healthcare professionals sponsored to foreign and regional symposia, conventions or CME events should be able and willing to lecture or share highlights of topics at local CME's. An agreement to this effect should be made between the sponsoring company and the healthcare professional. PHAP sponsors should assist their sponsored doctors in sharing their new knowledge at local events.

11.9 Company-Sponsored CME Events

11.9.1 Overseas
Pharmaceutical companies sponsoring doctors to overseas company stand alone meetings may sponsor no more than seven (7) doctors per event. At a level above this, the rationale of an overseas meeting vs. an in-country meeting is highly questionable.

11.9.2 Regional
Pharmaceutical companies may sponsor no more than twelve (12) healthcare professionals to regional company stand-alone scientific meetings. Regional events are described as those events held in ASEAN countries, Hong Kong, Taiwan, China, and Korea.

11.9.3 Local
Locally company sponsored CME events must be held in business accommodation locations, and not primarily resort locations.

The scientific program must constitute a minimum of 66% of the time in the given location and/or locations before or after the scientific agenda, outside of reasonable travel time. Invitations should be extended only to healthcare professionals in relevant therapeutic areas related to the scientific content.

Under no circumstances is a pharmaceutical company allowed to pay expenses for spouses or family, an exception being a spouse medically qualified and practicing in a therapeutic area relevant to the scientific meeting or society.

Support of raffles with high value items (over P1000.00) is totally inappropriate.

The use of a star talent should not be used to attract participants to the meeting.

11.9.4. Pharmaceutical companies must encourage their sponsored healthcare professional to attend a major part of the CME event.

12.0 Medical Society Sponsored Activities

12.1 Member companies should not specifically support sports events such as golf tournaments or any charity or fund raising activities like movie premieres.

12.2 For fellowship nights etc., if the event is clearly a part of a scientific meeting, sponsorship is acceptable as long as it is on a modest scale and does not involve star talent that would attract public attention.

13.0 Relationship Building

13.1 No company may sponsor or entertain a healthcare professional at activities considered professionally, morally or legally inappropriate.

13.2 Simple inexpensive business meals and cocktails for healthcare professional are allowed.

14.0 Independence of Healthcare Professionals

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 have an inappropriate influence on a healthcare professional's prescribing practices. The only exceptions are:

14.1 Pieces of equipment, tools, devices, computers and educational materials may be donated or loaned to medical training institutions and hospitals, but not to an individual or individuals. Items for donation must have direct use in medical care and diagnosis, e.g., ECG machines, stethoscopes, x-ray machines/films, scanners, diagnostic equipment. Pieces of business machines and appliances are not allowed for donation, i.e., communications equipment (such as fax, pagers, cellular phones), furniture and air conditioners.

14.2 For cultural reasons, on Christmas and birthdays, gifts of moderate value may be given to healthcare professionals even if these gifts are unrelated to the practice of medicine – (retail price should not be more than Php1500).

15.0 Activities related to Clinical Trials

This section covers the conduct of investigator's meetings and presentations related to clinical trials sponsored by pharmaceutical companies held locally or outside the country.

15.1 Clinical trials are scientific investigations using valid study designs conducted according to protocols or study descriptions approved by BFAD or a duly established independent institutional review board or Ethics Committee.

15.2 Sponsorship to clinical trial investigator's meetings and presentations are allowed subject to the following provisions:

15.3 Sections 11.2, 11.4, 11.6 and 11.9.1, 11.9.2, 11.9.3, 11.9.4 are deemed to apply.

15.4 For investigator's meetings/presentations held outside the country, the limits set forth in Section 11.8.1 apply prior to the approval of the study protocol or description.

15.5 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.

15.6 For clinical trials conducted solely in the Philippines, investigators' meetings 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 not to exceed limits prescribed under Section 11.8.1. Honoraria not to exceed USD 100 per day may be given to each sponsored healthcare professional.

15.7 Post-marketing Surveillance is subject to the PMS Guidelines described in Appendix 2.

16.0 Communications with the General Public
(note: refer to –GUIDELINES ON COMMUNICATION OF PRESCRIPTION PRODUCTS TO THE GENERAL PUBLIC: Appendix 1

16.1 Inquiries regarding the use of pharmaceutical products may be construed as a practice of medicine hence this must be handled by appropriately qualified personnel like the Product Manager or Medical Director. Request for advice on diagnosis and treatment must always be referred to a healthcare professional.

16.2 The current trend is the rapid transfer of information, awareness and education on the health risks of certain diseases like coronary heart disease, diabetes, smoking, respiratory diseases, HIV, tuberculosis, gastrointestinal infection, obesity, influenza, cancer, osteoporosis, menopause, stress, depression, etc.

Infomercial covering medical and healthcare topics and treatment options is permitted as long as its content is medically sound does not encourage self-medication, directs the readers to consult a doctor and treatment options are balanced with information on contraindications, precautions, warnings and/or side effects.

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

16.4 Any activity directed to the general public which encourages a patient to consult a healthcare professional for a specific illness is allowed as long as no specific brand is being mentioned. Generic names are permissible in press materials but brand names are not allowed in paid advertising, such as advertorials.

16.5 For public service announcements on product withdrawals, batch problems, batch mix-up, new warnings about a product which may have serious public health implications, brand names together with the corresponding generic names may be used.

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

16.7 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.

16.8 The material must contain a statement directing the patient to seek further information from his healthcare professional.

16.9 Patient Aids

Once a decision to prescribe that product has been made, patient aids which 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 which clarifies method of administration, precautions, special instructions. Patient aids must not make comparisons or include promotional claims. To ensure compliance, patient aids must be administered by appropriate healthcare professional.

16.10 The tone of material must not cause unnecessary alarm or misunderstanding nor must it cause unfounded hopes of successful treatment or stimulating the demand for prescription of a particular product.

17.0 ADMINISTRATION OF THE CODE

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

17.1.1 In case of disputes between the Ethics Committee and a PHAP member, the PHAP member can appeal first to the Ethics Committee and if not satisfied to the Appeals Board.

17.1.2 The Appeals Board is made up of three (3) members of the PHAP Board and four (4) members from the Ethics Committee

17.2 Procedures

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

17.2.2 The following procedures shall apply in the event PHAP Ethics Committee receives a complaint alleging that a Member of PHAP has violated the Ethics Code.

17.2.2.1 Complaints may be from individuals, groups, or member companies of PHAP.

17.2.2.2 If a complaint is lodged with the PHAP Ethics Committee by a member of PHAP, it must have the written endorsement of the PHAP Delegate or Alternate.

17.2.3 Any complaint regarding violations of the PHAP Ethics Code shall be delivered directly to the Chair of the PHAP Ethics Committee, 18th Floor Trafalgar Plaza, 105 HV de La Costa Street, Salcedo Village, Makati City 1229.

17.2.4 On receipt of a complaint, the Chair of the Ethics Committee or his delegate shall acknowledge the complaint in writing within 7 days. All such complaints should be dealt with as expeditiously as possible

17.2.5 The Member that is the subject of the complaint (subject company) shall be given full details of the information lodged with PHAP Ethics Committee. The subject company will be invited to state within 10 days whether or not the information supporting the complaint is correct, and to give any answer or explanation which may be deemed necessary.

17.2.6 The subject company and the complainant may be asked to submit further information to facilitate the investigation of the complaint.

17.2.7 The information and response shall be provided to the PHAP Ethics Committee. The PHAP Ethics Committee will then review/study the complaint and the company's response in order to determine if there has been a violation or not.

17.2.8 The Chair of the PHAP Ethics Committee will advise the PHAP member of the Committee's decision whether there has been a violation or not. In case of violation, the specific section of the Code and the applicable sanction provided in Section 18 will be transmitted to the parties concerned with copy furnished the PHAP Board through the PHAP Secretariat.

17.2.9 If the company is not satisfied, an appeal may be filed to the Ethics Committee by the subject company within 10 working days following receipt of notification of the decision concerning a finding of breach. The right of appeal lapses if an appeal is not filed within this period.

17.2.10 If the company's appeal is not upheld by the Ethics Committee, a final appeal may be filed with the PHAP Appeals Board within 10 working days upon receiving notification from the Ethics Committee. The decision of the PHAP Appeals Board will be final and executory.

17.2.11 Inter-company complaints should not be used as a competitive tool.

17.3 Membership of the PHAP Ethics Committee shall primarily be drawn from people outside of the pharmaceutical industry.

17.4 The members of the PHAP Ethics Committee shall be the following; Chairman, Vice-Chairman and 7Members.

17.5 The PHAP Ethics Committee may call upon Technical Advisers or establish Working Committees as needed. Working Committees may include members from the pharmaceutical industry.

17.6 Complaints against companies that are not members of PHAP but whose parent company is a member of the IFPMA will also be decided by the same process outlined in Sections 17.1 to 17.5,

17.7 Complaints against companies who are not members of PHAP or under the umbrella of the IFPMA will be referred to BFAD or other proper Authorities.

18.0 SANCTIONS

18.1 Sanctions against a subject company may be applied where breaches of the Code of Conduct have been established. Sanctions may take the form of one or more of the following :

18.1.1 The requirement that the subject company take immediate action to discontinue or modify any practice which is determined to constitute a breach of the Code. Written notification of this action must be provided to the Ethics Committee within 5 working days of the receipt of the decision of the Committee.

18.1.2 Retraction statements, including corrective letters and advertising, to be issued by the subject company, subject to the approval of the Committee prior to release.

18.1.3 The issuing of a fine by the Committee to the subject company in accordance with Section 18.1.4 of the Code. The fine is To be paid within 30 days of being advised.

18.1.4 The schedule of fines that may be imposed by the Committee for breaches of the Code – see Appendix 3.

19.0 COMPLIANCE PROCEDURES

Its 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 embodies. This procedure should be documented and provided to relevant employees to further enhance Ethics Code compliance

20.0 Amendments

This Code may be amended by a simple majority 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

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17.2.9 If the company is not satisfied , an appeal may be filed to the Ethics Committee by the subject company within 10 working days following receipt of notification of the decision concerning a finding of breach. The right of appeal lapses if an appeal is not filed within this period.

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18.0 SANCTIONS

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