2017

PhAMA Code of Pharmaceutical Marketing Practices

For Prescription (Ethical) Products – Twentieth Edition

Contents

Introduction (↑)

The PhAMA Code of Pharmaceutical Marketing Practices was first drawn up and adopted by the membership in 1978. It has undergone constant review by the association and has been amended from time to time where necessary, to clarify it and bring it up-to-date.

Notwithstanding any provision made under the Code, all marketing activities under the Code must conform to all existing and relevant government legislation governing the practice of the Pharmaceutical Industry.

The Code owes its existence to the determination of the Association to voluntarily secure the acceptance and adoption of high standards of conduct in the marketing of pharmaceutical products which the industry makes available for prescription purposes to the public. For this reason, members of the Association have concurred in the promulgation of this Code and submitted to its restraints.

The Administration of complaints and the procedure, which sets time frames for processing each complaint lodged, is outlined in the Code.

The Code also includes explanatory notes to amplify the text and interpretation of the Code in some instances.

PhAMA, through its Ethics Committee shall be responsible for receiving and deliberating on all complaints, and in making decisions on each of them, and for communicating their decision to the complainant. The Ethics Committee shall publish the names of companies, which have been found to be in breach of the Code.

Therefore, the major sanction against any company that transgresses the Code is the sanction of adverse publicity.

The objective of the Code is to provide as clear as possible guidelines in disseminating accurate, fair and objective information to the medical and allied profession so that rational prescribing decisions can be made. In so doing, members are obliged to adopt the high standard of conduct and professionalism in the marketing of pharmaceutical products.

There are obvious difficulties in drawing up exacting standard for the Code, especially where the success of application depends not only on strict adherence by members, but also the co-operation of non-members in the medical and allied professions. Self-discipline and restraints are an integral part of the Code, which must be applied not only in spirit but as well as to the letter.

Companies outside the Association are strongly recommended to accept and observe the Code.

This Code of Pharmaceutical Marketing Practices supersedes the previous Code. There is a separate Code that regulates OTC products.

Provision of The Code (↑)

1. Objective & Scope (↑)

1.1. Objective (There is a separate Code that regulates OTC products)

The PhAMA Code sets out standards for the ethical promotion of pharmaceutical products to healthcare professionals to ensure that member companies' interactions with healthcare professionals, patient organizations and medical institutions are appropriate and perceived as such.

1.2. Scope (For the purposes of the PhAMA Code)

- "pharmaceutical product" means any pharmaceutical or biological product (irrespective of patent status and/or whether it is branded or not) which is intended to be used on the prescription of, or under the supervision of, a healthcare professional, and which is intended for use in the diagnosis, treatment or prevention of disease in humans, or to affect the structure or any function of the human body.
- "promotion" means any activity undertaken (or material prepared) by a member company or any third party acting on behalf of the company which is directed at healthcare professionals to promote the prescription, recommendation, supply, administration or consumption of its pharmaceutical product(s) through all 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.
- "patient organization" means typically a not-for-profit institution that primarily represents the interests and needs of patients, their families and and/or caregivers.
- "medical institution" means typically an organization that is comprised of healthcare professionals and/or that provides healthcare or conducts healthcare research.
- "company" means any company that is a member of PhAMA.

1.3. Exclusions

This Code does not seek to regulate the following activities:

- Promotion of self-medication products that are provided "over the counter" with or without prescription.
- Pricing or other trade terms for the supply of pharmaceutical products.
- The conduct of clinical trials.
- The provision of non-promotional information by member companies

2. General Principles (↑)

2.1. The healthcare and well-being of patients are the first priority for pharmaceutical companies.

2.2. Methods of Promotion

Methods of promotion or marketing must never be such as to incite unfavourable comments or to bring discredit upon, or reduce confidence in the pharmaceutical industry.

2.3. Basis of Interaction

Member companies' relationships with healthcare professionals are intended to benefit patients and to enhance the practice of medicine. Interactions should be focused on

informing healthcare professionals about products, providing scientific and educational information and supporting medical research and education.

2.4. Independence of Healthcare Professionals

No financial benefit or benefit-in-kind (including grants, sponsorships, gifts, 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.

2.5. Appropriate Use

Promotion should encourage the appropriate use of pharmaceutical products by presenting them objectively and without exaggerating their properties.

2.6. Transparency of Promotion

Promotion should not be disguised. Clinical assessments, post-marketing surveillance and experience programmers and post-authorization studies must not be disguised promotion. Such assessments, programmes and studies must be conducted with a primarily scientific or educational purpose. Materials relating to pharmaceutical products and their uses, whether promotion in nature or not which is sponsored by a company should clearly indicate by whom it has been sponsored.

2.7. Standards of Promotion

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.

2.8. Privacy Statement

Pharmaceutical companies will respect the privacy and personal information of patients.

3. Pre-Approval and Off-Label Communications (↑)

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

This provision is not intended to prevent the right of 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.

Only Medical/regulatory department of our member companies will respond to unsolicited queries pertaining to unapproved label use.

4. Standards of Promotional Information (↑)

4.1. Accurate and Not Misleading

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 (preferably less than 5 years old). It should not mislead by distortion, exaggeration, undue emphasis, omission or in any other way. Every effort should be made to avoid ambiguity.

Theoretical projection of that evidence should be avoided. Extrapolation of data from animal studies is not allowed.

4.2. Substantiation

Promotion should be capable of substantiation either by reference to the approved labelling or by scientific evidence. In addition, promotion and scientific evidence should be consistent with locally approved product indication. Such evidence should be made available on request to healthcare professionals. Companies should deal objectively with requests for information made in good faith and should provide data which are appropriate to the source of the inquiry.

4.3. Claims & Comparisons

Exaggerated or all-embracing claims must not be made and superlatives must not be used unless based on substantial scientific evidence and other responsible medical opinion. "Hanging" comparatives, which merely claim that a product is "better or stronger" etc., must not be used.

Claims should not imply that a pharmaceutical product or an active ingredient has some special merit, quality or property. Claims for superior potency per unit weight are meaningless and best avoided unless they can be linked with some practical advantage, e.g. reduction in side effects or cost of effective dosage.

Any statement about side effects should be specific and based on data approved by the DCA or on published data to which references are given. It must not be state that a product has no side effects, toxic hazards or risks of addiction. The word "safe" must not be used.

The word "new" should not be used to describe any product or presentation which has been generally available, or any therapeutic indication for which the product / indication has been registered in Malaysia for more than 18 months.

Brand names of products of other companies must not be used unless prior consent of the proprietors has been obtained.

4.4. Disparaging References

The products or services of other companies should not be disparaged either directly or by implication. Substantiated comparative claims inviting fair comparisons with a group of products or with other products in the same field are permissible, provided that such claims are not presented in a way which is likely to mislead, whether by distortion, undue emphasis or otherwise.

The clinical and scientific opinions of members of the medical and allied professions should not be disparaged either directly or by implication.

5. Printed Promotional Materials (↑)

5.1. All Printed Promotional Material, including Advertisements

All printed promotional materials, other than those covered in Article 5.3 below, must include:

- the brand name of the product;

- the active ingredients, using approved names where they exist;
- the name and address of the pharmaceutical company or its agent responsible for marketing the product;
- date of production of the advertisement; and
- "abbreviated prescribing information" which should include an approved indication together with the dosage and method of use; and a succinct statement of the contraindications, precautions and side effects.

*A minimum font size of 6 points is to be used for printed materials.

5.2. All Printed Promotional Material, other than those covered in Article 5.3 below, should also fulfil the following requirements:

- Promotional material such as mailings and journal advertisements and loose inserts must not be designed to disguise its real nature.
- Advertisements in journals should not be designed so as to resemble editorial material.
- Promotional material should conform, both in text and illustration, to canons of good taste and should recognise the professional standing of the recipient.
- All printed promotional material, including advertisements should include the name of the product (normally the brand name) generic name of the product and the date of production of the advertisement.
- Doctors' names or photographs must not be used in a prominent manner in promotional material or in any way that is contrary to the ethical Code of the medical profession.
- Promotional material should not imitate the devices, copy, slogans or general layout adopted by other companies in a way that is likely to mislead or confuse.
- Material and articles from the lay press should not be used as promotional material.
- Disclaimer statement "For Healthcare Professionals only" to be added to printed materials for the HCP targeted audience.

5.3. Reminder Advertisements

A "reminder" advertisement is defined as a short advertisement containing no more than the name of the product and a simple statement of indications to designate the therapeutic category of the product. For "reminder" advertisements, "abbreviated prescribing information" referred to in Article 5.1 above may be omitted.

5.4. Artwork, Graphics, Illustrations, etc. In Print and Other Media

Illustrations must not mislead as to the nature of the claims or comparisons being made, nor as to the purpose for which the product is used.

Artwork and graphics must conform to the letter and the spirit of the Code. Graphs and tables should be presented in such a way so as to give a clear, fair, balanced view of the matters with which they deal, and should only be included if they are relevant to the claims or comparisons being made.

Graph and tables must not be used in any way which might mislead, for example by the incompleteness or by the use of suppressed zeros or unusual scales.

If a graph has been adapted from a paper, it must be stated so. A graph can be adapted; provided it is clear and its true meaning is not distorted.

5.5. Reprints, Abstracts and Quotations in Print or Other Media

Material from medical literature or from personal communications received from doctors must accurately reflect the meaning of the author and the significance of the study (which should not be distorted by the addition of printed highlighting or underlining to give prominence to selected portions of the material).

Care must be taken to avoid ascribing claims or views relating to the medical products to authors when such claims or views no longer represent or may not represent the current view of the authors concerned.

5.6. Distribution of Promotional Material

Promotional material should only be sent or distributed to those categories of persons whose need for or interest in the particular information can reasonably be assumed, but must not exceed the categories sanctioned by law.

Any information with regards to the use of pharmaceutical products in clinics or industrial concerns must be addressed to Health Care Professionals (HCP).

No promotional material shall be issued unless the final text and layout have been certified by a senior official preferable from medical/regulatory department of the company, preferably a doctor or a pharmacist.

The certificate shall certify that the signatories have examined the material and that in their belief it is in accordance with all legal and ethical requirements of the Code.

Companies shall preserve all certificates, together with the material in the form certified, for not less than 3 years and produce them upon request from the Ethics Committee.

6. Electronic Materials, including Audio-Visuals (↑)

The same requirements shall apply to digital promotional materials (Interactive Virtual Aid – mobile applications) as apply to printed materials.

Specifically, in the case of pharmaceutical product related websites:

- the identity of the pharmaceutical company and of the intended audience should be readily apparent;
- the content should be appropriate for the intended audience;
- the presentation (content, links, etc.) should be appropriate and apparent to the intended audience; and
- country-specific information should comply with local laws and regulations.

7. Interactions with Healthcare Professionals (↑)

7.1. Events and Meetings

7.1.1. Scientific and Educational Objectives

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.

Any financial support of medical societies, hospitals and clinics' social event e.g. annual general meeting, annual dinner, family day, sports day, etc. in the form of donation and/or gifts are not allowed.

7.1.2. Events involving Foreign Travel

No company may organize or sponsor an Event for healthcare professionals that take place outside Malaysia, where the majority of the attendees are Malaysians. International scientific congresses and symposia that derive participants from different countries are therefore justified and permitted to be hosted in any of the countries that are represented by the delegate. (All sponsorship and meeting criteria still applies)

7.1.3. Dissemination of Information of Unapproved Product or Indication

7.1.3.1. Local Meetings inclusive of CMEs

Dissemination of scientific information for a pharmaceutical product or indication, which has not been approved for marketing by the Drug Control Authority (DCA), or for a registered product with a new unapproved indication can be undertaken by a member company provided:

- No brand name is mentioned.
- Declare that it is still unapproved in Malaysia.
- Organised under the auspices of a Professional body or hospital-based CME committee.
- Based on verifiable (e.g. poster/ abstract/publication) data or peer review reprints as a CME event endorsed by a professional body.
- Relevant permission from authorised bodies (if required).

7.1.3.2. International Meetings

Information provided at International meetings / Symposia / Congress held in Malaysia, which appear on exhibition stands or is distributed to participants at international scientific congresses and symposia may refer to pharmaceutical products which are not registered in Malaysia, or which are registered under different conditions, provided that the following conditions are observed:

- The meeting should be a truly international, scientific Event with a significant proportion of the speakers and attendees from countries other than the country where the Event takes place; (Article 7.2 of Code)
- Information (excluding promotional aids) for a pharmaceutical product not registered in Malaysia should be accompanied by a suitable statement indicating that the product/indications/dosage form is not registered and make clear that the product/indication/dosage is still unapproved in Malaysia;
- Information which refers to the prescribing information (indications, warnings etc.) authorized in a country or countries other than Malaysia but where the product is also registered, should be accompanied by an explanatory statement indicating that registration conditions differ internationally.

7.1.4. Appropriate Venue

All Events should be held in an appropriate venue that is conducive to the scientific or educational objective and the purpose of the Event or meeting.

Companies should not organize Events nor provide financial support including sponsoring HCPs to any event at renowned or venues not appropriate for purpose of

scientific education associated with leisure, golf, spa, island resorts (not accessible by land transport) and gaming activities. The venue should be:

- appropriate for the meeting (e.g. adequate facilities for the number of attendees/good internet access)
- appropriate and conducive to the scientific or educational objective and purpose of the event or meeting
- located so as to minimise travel for attendees
- having adequate security
- able to successfully withstand public and professional scrutiny.

7.1.5. Limits

Refreshments and/or meals incidental to the main purpose of the Event can only be provided:

- exclusively to participants of the Event; and
- if they are moderate and reasonable as judged by local standards.

7.1.6. Entertainment

No entertainment or other leisure or social activities should be provided or paid by member companies.

7.1.7. Other Activities

Lotteries/lucky draws should not be part of symposia/exhibitions/company organized smaller group meetings.

7.2. Sponsorships

Member companies may sponsor healthcare professionals to attend External International Events/meetings provided such sponsorship is in accordance with the following requirements:

- The Event complies with the requirements in this Code as described in Article 7.1;
- Sponsorship to healthcare professionals is limited to the payment of travel, meals, accommodation and registration fees;
- Only cover basic economy travel (if travelling time is less than 6 hours)
- Limited to maximum twice per year/company for each healthcare professional.
- The cost of the most direct route will be funded.
- No payments are made to compensate healthcare professionals for time spent in attending the Event; and
- Any sponsorship provided to individual healthcare professionals must not be conditional upon an obligation to prescribe, recommend, purchase, supply, administer or promote any pharmaceutical product.

7.3. Guest

Companies should not pay any costs associated with individuals accompanying invited healthcare professionals.

7.4. Fees for Services

Health care professionals may be engaged as consultants and advisors for services such as speaking at and/or chairing meetings and events, involvement in training services and participation at advisory board meetings where such participation involves remuneration.

The arrangements which cover these genuine consultancies or other services must, to the extent relevant to the particular arrangement, fulfil all the following criteria:

- a written contract or agreement must be agreed in advance of the commencement of the services which specifies the nature of the services to be provided and the basis for payment of those services;
- a legitimate need for the services must be clearly identified and documented in advance;
- the criteria for selecting consultants must be directly related to the identified need and the consultants must have the expertise necessary to provide the service;
- the number of consultants retained must not be greater than the number reasonably necessary to achieve the identified need;
- 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; and
- the fair market value of the services provided is RM1,500.00/engagement/day with up to maximum RM3,000.00/multiple engagement/day.
- If it concerns local speakers at international events held locally or outside Malaysia, members are advised to refer to their own company's internal Code. The same proposal on a signed contract remains.
- If it concerns international speakers, then members are advised to check with the speaker's home country Code and apply accordingly. The same proposal on a signed contract remains.

7.5. Marketing Research

7.5.1. Methods Employed

Methods employed for marketing research must never be such as to bring discredit upon or to reduce confidence in the pharmaceutical industry. This provision applies whether the research is carried out directly by the company concerned or by an organisation acting on the company's behalf.

7.5.2. Questions

Questions intended to solicit disparaging references to competing products or companies must be avoided.

7.5.3. Incentives

Any incentives offered to the informants should be kept to a minimum and be commensurate with the work involved.

7.5.4. Transparency

Marketing research must not in any circumstances be used as a disguised form of sales promotion.

7.5.5. Objective

Marketing research must not have the direct objective of influencing opinions of the informant.

7.5.6. Identity of Informant

The identity of an informant must be treated as confidential, unless he has specifically agreed otherwise.

(In the absence of this agreement, it follows that the information provided as distinct from the overall results of the research must not be used as the basis upon which a subsequent approach is made to that informant for the purpose of sales promotion.)

7.6. Gifts and Other Items

Inappropriate financial or material benefits, including inappropriate hospitality, should not be offered to healthcare professionals to influence them in the prescription of pharmaceutical products.

Any financial support of medical societies, hospitals and clinics' social event e.g. annual general meeting, annual dinner, family day, sports day, etc. in the form of donation and/or gifts are not allowed.

7.6.1. Prohibition of Cash and Personal Gifts

Payments in cash or cash equivalents (such as gift certificates) must not be provided or offered to healthcare professionals. Gifts for the personal benefit of healthcare professionals (such as sporting or entertainment tickets, electronics items, etc.) must not be provided or offered.

7.6.2. Promotional Aids

Promotional aids whether related to a particular product or of general utility, may be distributed provided the promotional aid is of small value (not more than RM100.00) and directly relevant to the practice of medicine or pharmacy or of benefit to patient care.

7.6.2.1. Reminders are designed just to remind a prescriber of a product's existence and must not contain a promotional claim which includes the mention of any indication. A reminder must contain:

a) Brand name of the product;
b) Approved name(s) of the active ingredients(s);
c) Name of the supplier.

7.6.2.2. If a reminder contains tag lines or slogans, the name of supplier as well as a statement that further information is available on requests, must be included.

7.6.3. Educational Materials and Items of Medical Utility

Items of medical utility may be offered or provided, provided that such items are of modest value, do not exceed RM500.00, do not offset routine business practices and are beneficial to the provision of medical services and for patient care.

For medical educational material, e.g. journals, textbook & anatomy models, the limit is up to RM1,000.00/year for institutions only.

The items provided are of direct educational value and have no direct promotional value.

It is acceptable to print/put the company's logo on any educational materials or items of medical utility. Brand names are however not allowed.

7.6.4. Cultural Courtesy

An inexpensive cultural courtesy item of not more than RM100.00 such as cakes, cookies, dates and mandarin oranges may be given to healthcare professionals, in acknowledgement of significant festive occasions. Each HCPs should only be offered a maximum of two such gifts/year.

8. Samples (↑)

8.1. Samples of products given out should be no larger than the smallest commercial pack of each strength and clearly labelled as "Samples – Not for Sale" or similar wording allowed by the law.

8.2. Where samples of products restricted by law to supply on prescription are distributed by a representative, the sample must be handed direct to the doctor or given to a person authorised to receive the sample on his behalf.

8.3. Samples must be delivered conforming to the Postal and Poisons Regulations governing it, and must be packed so as to be reasonably secure against the package being opened by children. (Refer to the Ethics Committee & RAC)

8.4. Samples must not be used as unofficial bonus and an inducement to purchase. It must also not be used for clinical trials. Samples of medicines should not be sold by anyone and should be used as intended to enable prescribers to gain experience with its use.

8.5. Control and Accountability

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 the possession of medical representatives. In any case where the Member Company is in knowledge of misused of samples, the member company has the right to discontinue sample distribution.

9. Clinical Research and Transparency (↑)

9.1. Transparency

Companies are committed to the transparency of clinical trials which they sponsor. It is recognized that there are important public health benefits associated with making clinical trial information more publicly available to healthcare practitioners, patients, and regulatory agencies. Such disclosure, however, must maintain protection for individual privacy, intellectual property and contract rights, as well as conform to legislation and current national practices in patent law.

9.2. Distinct from Promotion

All human subject research must have a legitimate scientific purpose. Human subject research, including clinical trials and observational studies, must not be disguised promotion.

10. Support for Continuing Medical Education (↑)

Continuing medical education (CME) helps ensure that healthcare professionals obtain the latest and most accurate information and insights on therapeutic areas and related interventions that are critical to the improvement of patient care and overall enhancement of the healthcare system. The primary purpose of an educational meeting must be the enhancement of medical knowledge and therefore financial support from companies is appropriate.

When companies provide content to CME activities and programs, such material must be fair, balanced and objective, and designed to allow the expression of diverse theories and recognized opinions. Content must consist of medical, scientific or other information that can contribute to enhancing patient care.

On a professional basis, a doctor or pharmacist under the employment of a member company is allowed to attend Scientific meetings under the umbrella of a professional Society or Organisation of which he is a member (e.g. MMA, MPS) even though it may be organized by a competitor company.

11. Grants & Donations (↑)

Donations are for charitable purposes and for charitable organisations.

Grants are provided to support educational programmes (including but not limited to requests to fund CME programmes, educational programmes, fellowships, advocacy organisations, societies, medical conferences and congresses) if they are:

- Unsolicited
- From an institution or organisation, not from an individual
- Unrelated to the prescribing, purchasing, registration of any products
- Substantiated by written documentation of details of programme
- Able to withstand public scrutiny

As a general rule, grants and donations should not be provided for the purpose of supporting a recipient's ordinary business expenses, e.g. for infrastructure or overhead (such as the purchase, construction, expansion, or modification of facilities or equipment and paying of salaries).

Institutions or organisations must ensure that the recipients use the donations and grants in accordance with the intended purposes independent from the companies providing the grants and donations. This does not cover grants and donations for clinical research.

12. Interactions with Patient Organizations (↑)

12.1. Scope

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.

12.2. Declaration of Involvement

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. No company may require that it be the sole funder of the patient organization or any of its programs.

12.3. Written Documentation

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.

12.4. Events

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.

12.5. Disease Awareness

Member companies may support public disease awareness campaigns by providing support or sponsorship or partnership with appropriate medical associations. Such disease awareness campaigns should not be misused as any forms of disguised

promotions. Disease education activities may provide information, promote awareness and educate public about health, disease and their management

a) All information provided to public must comply with Article 12 of this Code.
b) Activities must not include any reference to a specific prescription product.
c) The emphasis of disease education activity should be on the condition and its recognition rather than on the treatment options.
d) If discussed, the management options should be presented in a comprehensive, balanced and fair manner.
e) Companies must ensure that the venue and locations is appropriate and conducive to informational communication.

13. Relations with The General Public and Lay Communication Media (↑)

13.1. Request from individual members of the public for information or advice on personal medical matters must always be refused and the inquirer recommended to consult his or her own doctor.

13.2. Promotional material issued for distribution or display anywhere to which the public has access must not include any message likely to arouse a demand for all Scheduled Poisons.

13.3. Patient education leaflet related to disease condition must be fair, unbiased and not contain any product name and restrict reference to the company providing the leaflet to its name & logo. Therapeutic class/option or chemical name of drug or generic class is allowed, as long as it is unbiased.

13.4. Leaflets for instruction in the use of a specific medicine containing reference to the name and illustration of the product must only be provided to the public by a medically qualified practitioner or health care professional.

13.5. Use of Social Media Communication

All Social Media Communication for business purposes should be communicated from a Company Profile and not associated to Personal Account.

All information shared in Social Media for business purposes need to be appropriate, accurate and fair for public viewing and understanding.

Information including:

- A product name/logo (either brand or generic) is not allowed as direct to consumer promotion is prohibited.
- Any description that could refer only to a specific product (e.g. a therapeutic class in which there is only one product) is not allowed as well.
- A disease area/indication will need to be reviewed and approved by the relevant function in accordance to the approval process of the respective member company.
- Company branding should be shared in the social media platform for transparency.

If required, the information shared should be accompanied with referencing, scientific disclosure, conflict of interest and privacy statement.

Member companies are responsible for the information uploaded onto their website.

14. Company Procedures and Responsibilities (↑)

14.1. Procedures

Companies should establish and maintain appropriate procedures to ensure compliance with relevant Codes and applicable laws and to review and monitor all their activities and materials in that regard.

14.2. Medical Representatives

- Medical representatives must be adequately trained and possess sufficient medical and technical knowledge to present information on the company's products in an accurate and responsible manner.
- Medical representatives should at all times maintain a high standard of ethical conduct in the discharge of their duties. They are required to be instructed in and possess a copy of the Code.
- The requirements of the Code which aims at accuracy, fairness, balance and good taste apply to verbal representations as well as printed material.
- Medical representatives must not employ any inducement or subterfuge to gain an interview. No payment of a fee should be made for the grant of an interview.
- A company will assume responsibility, under the Code, for correcting breaches of the Code resulting from misconduct or misrepresentation of fact by any representative.
- The system of remuneration of representatives should not be such as to adversely influence the proper prescription and usage of pharmaceutical products.

(The provision relating to remuneration is intended to ensure that no incentives are provided that would lead to unethical behaviour of representatives, and not whether a fixed salary or bonus system is used for compensation)

14.3. Responsibilities for Approving Promotional Communications

A designated company employee with sufficient knowledge and appropriate qualifications should be responsible for approving all promotional communications. In the alternative, a senior company employee(s) could be made responsible provided that he or she receives scientific advice on such communications from adequately qualified scientific personnel.

15. Infringement, Complaints, and Enforcement (↑)

15.1. Complaints

Genuine complaints relating to infringements of the PhAMA Code are encouraged. Detailed procedures for complaints and the handling of complaints (including the respective roles and jurisdiction of PhAMA and member associations) are set out in Appendix 1: Operation of The Code.

15.2. Measures to Ensure and Enforce Compliance

Each member company is strongly encouraged to adopt procedures to assure adherence to the PhAMA Code of Conduct. While strong legal and regulatory mechanisms and vigorous government enforcement may obviate the need for compliance mechanisms, member companies are encouraged, where appropriate; to include provisions intended to assure compliance with PhAMA Code of Conduct.

16. Valid Patent Rights (↑)

All valid patent rights of products and processes must be respected by members.

Appendix 1 (↑)

Operation of The Code

1. Any complainant company should first initiate contact with the company alleged to be in breach, in order to discuss the issue and endeavour to settle the dispute / disagreement of any subject matter, prior to forwarding such complaints in writing to the Ethics Committee for deliberation.

   The complainant should provide proof or evidence that the parties concerned have communicated but were unable to come to a decision, when lodging a complaint.

   (This is to encourage companies to talk to one another, in order to attempt to amicably settle any issues. Often, CEO's are not aware of such complaints. CEOs should be responsible for activities within their respective companies.)

   Every case should be treated as a fresh complaint; however, the Ethics Committee has the right as provided for in the PhAMA Code of Conduct to proceed without insisting on prior communication between two parties in cases of repeated breaches.

   The term 'repeat breaches' is defined as being 'the breaches of the same section or sections of the Code with the same product claim'.

   A penalty of up to RM100,000.00 will be meted out to repeat offenders.

   In cases of repeated breaches of the same section or sections of the PhAMA Code of Pharmaceutical Marketing Practice, the complainant may choose not to communicate further with the defendant prior to lodging a formal complaint. If so, the Ethics Committee has the absolute discretion to decide if the case should be considered.

   All alleged breaches in the observance of the Code against any member reported to PhAMA, must be made in writing and submitted by the CEO of the complainant company (in order that the CEO of that company is aware that a complaint has been submitted) together with an administrative fee of RM3,000.00 to PhAMA. The administrative fee cannot be used to offset the fine. It will first be validated to ensure that:

   It appears to be a genuine matter, submitted in good faith.

   - There is sufficient evidence to enable the complaint to be processed.
   - It is not a duplicate of a case, which has already been resolved under the Code.

   The minimum information required is:

   - A specific reference to the source of the advertisement / activity which is the subject of the complaint and the name of the product and products involved.
   - The identity of the company concerned with the alleged breach of the Code.
   - The date of the alleged breach of the Code.
   - Section(s) of the Code alleged to be breached.

   Where the case concerns printed promotional material, the complainant is asked to provide copies of the offending material. Where the case concerns an activity, if there is no documented proof, this needs to be reported by or confirmed by an independent witness.

2. The Ethics Committee shall meet soonest after the receipt of the complaint from the Secretariat to decide if there is a case for the subject company to answer.

3. In the event that the Ethics Committee decided that there is a case to be answered, the companies must submit the relevant copies required of the referenced documents and highlight the relevant sections in its response to support its case.

   All documents from the plaintiff and defendant, pertaining to the cases lodged to the Ethics & Marketing Practices Committee must be submitted in 20 copies.

   The Committee may decide not to preside over the case should the required number of copies not be made available.

   The Plaintiff and Defendant will be called to the Ethics & Marketing Practices Committee's case deliberation meetings, if there is a need for information to be presented that has not been presented in written form.

   During the deliberation of the Ethics Committee, the Defendant & Plaintiff may make representation to the Committee, limited to one person to a period of not more than 10 minutes, unless more time is requested by the Committee.

4. The company judged to be in breach of the Code will be asked to discontinue the offending material or practice. Nor must the offending text be employed in any other media e.g. if promotional literature is in breach, the offending text cannot be used in journal advertisements, mailings etc. In addition, the company may be required to issue a Retraction Statement, details of which will be determined by the Ethics Committee. The Ethics Committee may at its discretion recommend to the PhAMA Board of Directors to also notify the Medicine Advertisements Board (MAB) and / or the Drug Control Authority (DCA).

   (The Board will only endorse the decisions made by the Ethics & Marketing Practices Committee and the Ethics Appeal Committee. It suffices for the decisions to be e-mailed to the Board prior to forwarding them to the relevant parties).

   The Committee will not publicly disclose the Ethics Case decisions to the public. The Committee may however inform members of the findings, together with the name of companies involved quarterly.

   The Committee may inform the regional office regardless of whether there is compliance to the Ethics Committee's decision.

5. Appeals can only be made on the merits of the case and should be made within two weeks of receipt of the formal notice of the Committee's decisions, after which, the party concerns, loses the right to appeal.

   The appeals fee is RM3,000.00. The complainant does not have any right to appeal (where defendant is found not guilty). In such a case, should the plaintiff like to pursue the issue, the plaintiff would be required to lodge a separate complaint.

   In the event that there is no appeal against the Committee's decision by the defendant within 2 weeks of receipt of this decision, the complainant's administrative fee of RM3,000.00 will be refunded/forfeited depending on the Committee's findings. The defendant if found to be in breach will be fined up to RM50,000.00 or RM100,000.00*. (See Appendix B)

6. If the defendant is found not guilty, the complainant's administrative fee of RM3,000.00 will be forfeited.

If the defendant company wishes to appeal against the Committee's decision, the appeal accompanied with an administrative fee of RM3,000.00 should be submitted to the Secretariat within 2 weeks of receipt of the decision, provided that the company undertakes to discontinue the offending material or practice and the text should not be reproduced in any other media (See Article 3 above) pending a decision on the appeal. (The administrative fee of RM3,000.00 is to contribute towards the cost of outside advice).

7. The appeal will be considered by the Ethics Appeal Committee, which may include personal representation by the company. The Committee may also invite external sources of advice. The cost of such fees will be borne by the fees submitted by the appellant. (Appendix C provides the guidelines for operations of the Ethics Appeal Committee).

   The Ethics Appeal Committee shall only preside on section(s) which was initially raised at the regular Ethics & Marketing Practices Committee only.

   (Should the plaintiff like to forward a new section(s) for deliberation, the plaintiff shall lodge a fresh complaint, and submit the lodging fee of RM3,000.00 to the regular Ethics & Marketing Practices Committee).

8. In the event that the Ethics Appeal Committee decides that there is a case to be answered, the company judged to be in breach of the Code will be asked to give an undertaking to withdraw the offending material or discontinue the practice. In addition, the company may be required to issue a retraction statement, details of which will be determined by the Ethics Committee. The subject company's administrative fee of RM3,000.00 will be forfeited, and the complainant's administrative fee of RM3,000.00 will be refunded.

   The administrative fee cannot be used to offset the fine.

   In the event that the Ethics Appeal Committee decides that there is no case to be answered, the company judged will have the earlier decision of the Ethics Committee reversed. The administrative fee of RM3,000.00 will be refunded to the subject company, while the complainant company's administrative fee of RM 3,000.00 will be forfeited.

9. If a reply is not received confirming acceptance of the Ethics Committee's decision or the Ethics Appeal Committee's decision and providing the undertaking requested by the Committee within 3 weeks of receipt of the decision, it will be taken that the company has refused to abide by the decision.
10. If the company refuses to abide by the decision of the Ethics Committee or the Ethics Appeal Committee, the Board of Directors may apply the following sanctions:
    10.1. In the case of international companies, the matter will be referred to the Head Office of the Company, informing it of the case and the Board of Director's decision and appealing to the Head Office to persuade their subsidiary to comply by withdrawing the offending material or discontinuing the practice not later than 4 weeks from the date of the communication.
        10.1.1. In the interim, the subject company is suspended from membership for the same 4 weeks' period under Rule 10(A) of the PhAMA Rules and Constitution.
        10.1.2. If no indication of the withdrawal of the material or discontinuance of the practice is received by the set deadline, then the Board of Directors may:
            - Inform the IFPMA** on the matter.
            - Suspend the company under Rule 10(A) for a period up to the date of an Extraordinary General Meeting convened under Rule 11.

- Take action under Rule 11 for the expulsion of the subject company from the Association.

10.1.3. In the case of other companies, the Board of Directors will:

- Suspend the company under Rule 10(A) for a period up to the date of an Extraordinary General Meeting convened under Rule 11, and;
- Take action under Rule 11 for the expulsion of the subject company from the Association.

11. The decision of the Board of Directors in the matter shall be final and information on above sanctions may be made known to the Medicine Advertisements Board (MAB) and / or the Drug Control Authority (DCA), as well as Script, Market Letter and any other relevant publication, and included in the regular reports of the Ethics Committee and the Annual Report of the Board of Directors to members.
12. The Ethics Committee and the Ethics Appeal Committee reserves the right to release the whole or part of the information relating to the complaint and its resolution to any interested person or bodies as it may so decide.
13. Any details of complaints on alleged breaches of the Code, the decisions of the Ethics Committee and the Ethics Appeal Committee and subsequent actions taken by all parties in the matter may not be used by the complainant or the subject company for any publicity or promotional purposes.
14. The Ethics Committee, the Ethics Appeal Committee, the Board of Directors, PhAMA and its staff, including individuals serving in any capacity in these committees, shall not be subject to any legal action by any party on decisions taken relating to the complaint.
15. Procedure Review for 3rd party complaints
    15.1. Complaints by third party would be dealt with in a similar procedure to a member company to member company complaint.
    15.2. The following procedures would be adopted, for complaints by a third party (company / individual / any other organisation).
    15.3. If the company being complaint is not a member of PhAMA, PhAMA will revert to the complainant and request that it lodge a complaint against the relevant trade associations concern.
    15.4. On receiving the complaint against a member company of PhAMA, the Committee will revert to advise the complainant to contact the defendant directly in order to settle the matter amicably, prior to forwarding such complaints in writing to the Ethics Committee for deliberations.
    15.5. Should the parties concern have communicated but were unable to come to a decision, and the complaint comes back to the Ethics & Marketing Practices Committee and the Committee will deliberate on the case.
    (In such an event, both complainant and defendant must submit 10 copies of all relevant documents and highlight the relevant sections in its response to support its case.)
    15.6. The Plaintiff also has a right to appeal provided they pay the RM3,000.00 appeals fee.

* In cases of repeated breaches of the same section or sections of the PhAMA Code of Conduct with the same product claim.

** The International Federation of Pharmaceutical Manufacturers Associations (IFPMA) is an international federation to which PhAMA is affiliated.

Appendix Ai (↑)

PhAMA Ethics Case Review Committee – Normal Case

Role	Position	No
Chairman	Director of the Board	1
Committee members	Pharmacists Marketing Personnel Compliance Officers Medical Doctors	Min 3
Secretariat Staff	Executive Director Manager	Min 1
External Representation by MMA	(By invitation only)	1

Punitive Action

1. As per "Operation of
2. For repetitive cases, the committee will advise the DCA/MAB for assistance to enforce its decision.
3. A heavier penalty of up to RM100,000.00 will be meted out in cases of repeat breaches of the same clause or clauses of the Code of Conduct.
4. Committee members who are not a Medical doctor nor pharmacist may attend the case deliberations meeting. However, only one vote/company is allowed at any one time.

Note:

- BOD: PhAMA Board of Directors
- MMA: Malaysian Medical Association
- MPS: Malaysian Pharmaceutical Society
- BC: Bar Council
- MAB: Medicine Advertisements Board
- DCA: Drug Control Authority

Appendix Aii (↑)

PhAMA Ethics Appeal Committee – Appeal Case

Role	Position	No
Chairman	Director of the Board	1
Committee member	Ethics Committee Chairman	1
Committee members	Pharmacists Marketing Personnel Compliance Officers Medical Doctors	Min 2
Secretariat Staff	Executive Director Manager	Min 1
External Representation by MPS, MMA & BAR Council	(By invitation only)	1 each

Punitive Action

1. As per "Operation of
2. The Committee may, at its discretion, cc its letter to the MAB/DCA for information.
3. The Committee may at its discretion, cc the company's Regional Office/Head office for information.

Note:

- BOD: PhAMA Board of Directors
- MMA: Malaysian Medical Association
- MPS: Malaysian Pharmaceutical Society
- BC: Bar Council
- MAB: Medicine Advertisements Board
- DCA: Drug Control Authority

Appendix B (↑)

1. Pre-Official Complaint

1.1. Company A and Company B to discuss the case prior to any formal complaint to the Ethics Committee, in the endeavour to settle the dispute or disagreement. Engagement must be made within the knowledge of the companies' respective country leads or person of equivalent position.

1.2. Prior to escalating the matter to PhAMA, the Plaintiff is to provide notification to defendant that it intends to do so after 14 working days from the date of the defendant's receipt of the notification; should no settlement or agreement be reached within the stipulated 14 days' time frame.

2. Official Complaint

2.1. Evaluation as to whether there is a case to be deliberated, will be made by the Executive Director upon receipt of the case complaint document. The document will be evaluated to ensure that the complaint logged is within the ambit of the PhAMA Code of Conduct and thus within the jurisdiction of the Ethics Committee to deliberate upon.

2.2. PhAMA will send a notification of receipt of the complaint documents to the plaintiff, defendant as well as chairperson of the Ethics Committee. All parties in receipt of the notification are to revert to PhAMA with acknowledgement within 7 working days of receipt of the document.

3. Ethics Case Review Panel Session

3.1. An Ethics Case Review Panel meeting to table and deliberate on the case will be identified by PhAMA based on the availability of chairperson and those who may form a case review panel. PhAMA may invite two persons who are staffs of the company concerned to represent the company during the hearing. Time and duration of representation by the two affected parties will be decided by the case review panel in session, based on the complexity of the case and the amount of information required.

3.2. Representations, deliberation and decisions made during the hearing sessions should be based on the spirit of the Code and not on technicalities.

3.3. The Ethics Case Review Panel may postpone making any decision should the committee so felt that it requires more time and/or information before deliberating on the case further. Another case review panel meeting may be held thereafter.

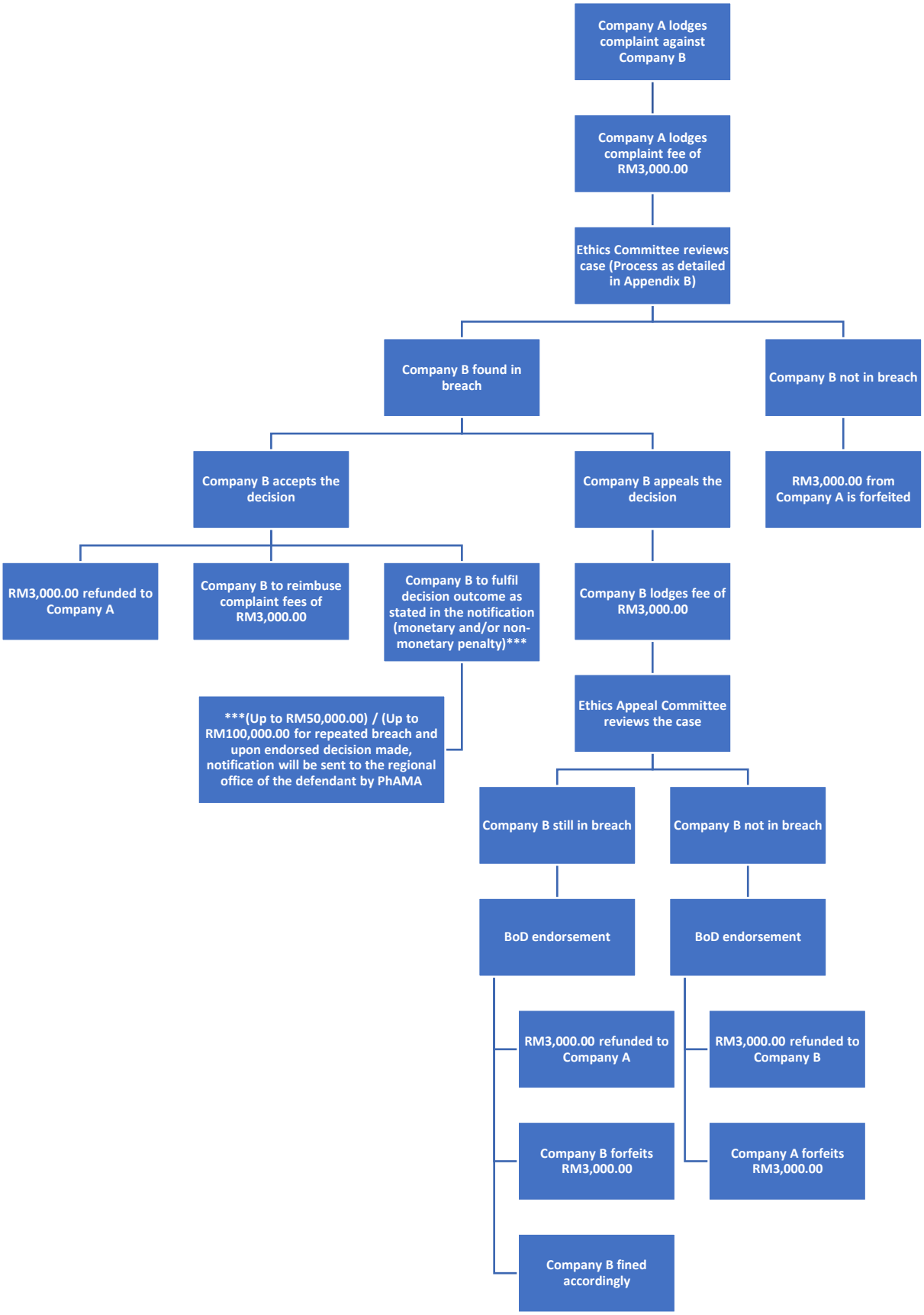
4. Post Ethics Case Review Panel Session

4.1. Ethics Case Review Panel's decision will be communicated to the plaintiff and the defendant after communication to the Board, for purpose of information only; unless the complexity of the case is as such that the panel requires direction and guidance from the Board, in which case, the matter will be escalated to the Board at its meeting, before proceeding further.

4.2. Decisions are to be communicated to the plaintiff and defendant within a month of a Case Review Panel's decision.

4.3. Plaintiff and defendant are to acknowledge receipt of the Case Review Panel decision.

Summary of Ethics Review Procedure



Appendix C (↑)

The Use of The Internet for Pharmaceutical Information - The PhAMA/IFPMA Position

The Internet has the potential to be a vital and positive resource for society. Although it is continuing to evolve, it has already demonstrated its remarkable ability to inform and educate global audiences on a wide range of subjects including health care and medicinal products.

- The research-based pharmaceutical industry, represented by PhAMA and the International Federation of Pharmaceutical Manufacturers Associations (IFPMA), strongly supports the right to use the Internet as a means for providing accurate and scientifically reliable information on medicines in a responsible manner, for the benefit of both patients and healthcare professionals.
- Measures to regulate the Internet require caution as they could inadvertently impose unacceptable constraints on legitimate communication and information flow. The unscrupulous will always evade controls whilst the law-abiding will comply. Inappropriate regulation could result in a situation where unregulated and unreliable sources of information remain on the Internet, unchallenged by reliable, authentic sources and legal authorities.

Regulation and Self-Regulation

- PhAMA has a long tradition and experience of self-regulation, self-auditing and the implementation of the Code of Conduct, which governs marketing and promotional practices. PhAMA is convinced that self-regulation is the method of choice for controlling the type and quality of information provided by pharmaceutical companies via the Internet, on pharmaceutical products.
- Wherever they market their products, pharmaceutical companies within the membership of PhAMA/IFPMA are bound by the self-regulatory PhAMA / IFPMA Code. The Code sets out principles and standards for the information provided by companies about their products, and these requirements are equally valid for and applicable to information made available via the Internet.

Sale and Supply via The Internet

- PhAMA/IFPMA shares concerns that the Internet can be misused by the unscrupulous, as a means to by-pass normal controls and to sell prescription medicines directly to patients, without appropriate professional consultation. Patients' health may be put at risk by such practices and industry supports measures to prevent such activities and to educate consumers about the dangers of procuring medicines in this way.
- Other forms of commerce involving the sale and supply of medicines via the Internet may also result in medicines being handled outside regulated distribution channels, with the danger that poor quality products, unlicensed medicines and counterfeits will be supplied.
- The nature of the Internet makes it difficult to enforce effective controls over those who misuse the Internet to advertise illegal and undesirable services and products. Regulation and enforcement activities by the government should, therefore, focus on the physical movement of products via vendors, agents and dealers who are handling medicines and distributing them outside of legitimate, approved channels.
- PhAMA recognises its responsibility to ensure that its products are only provided through legitimate and reputable channels. PhAMA has and will continue to work co-operatively with the government, regulatory bodies, and any other agencies to prevent the sale of medical products outside lawful distribution channels.

Future Challenges

PhAMA/IFPMA recognises the healthcare challenges presented by the global dimensions of the information available on the Internet but believe that these should be regarded as an opportunity for constructive changes, with the interests of the patient / consumer as the priority.

- Patients and consumers are seeking more information about medicines and medical treatment but laws and regulations differ widely throughout the world, with regard to the information which may be provided by companies on the products that they supply.
- Similarly, patients in remote areas, the elderly and incapacitated are seeking better access to medicines but there are major differences in the acceptability of "distance selling," even with appropriate safeguards for prescription controls.

Laws, regulations and medical culture differ in different parts of the world and the evolution of the Internet has brought the need for greater harmonisation into sharp focus. Greater uniformity in the international norms for disseminating accurate and reliable information on the use and availability of pharmaceutical products would make implementation and enforcement a much more tangible goal to the benefit of the patient / consumer and healthcare providers in all regions and in Malaysia.

Questions & Answers (↑)

The questions and answers section has been developed to provide clarity on the scope and provisions of the IFPMA Code. The content in this section is binding.

1. Communications with The Public (↑)

1.1. Q: Does the PhAMA Code regulate communications with the public?
A: No. The PhAMA Code covers interactions with healthcare professionals and the promotion of pharmaceutical products. Where direct promotion to the public, patient organization, medical institution is allowed, this is covered by local laws, regulations and/or relevant Codes of practice. Member companies should of course, comply with these local laws, regulations and/or Codes.
Note: This is addressed in Article 1 of the Provision of the Code.

1.2. Q: Does Medicine Advertisement Board's (MAB) approval take precedence over the PhAMA Code of Conduct even if the advertisement is not in the spirit of the Code?
A: The Ethics & Marketing Practices Committee reviews and deliberates each case based on its merits irrespective of MAB's approval. Such matters should be forwarded to the Ethics Case Review Committee, via the normal complaint processes.

2. Generic Ethical Products (↑)

Q: Does the PhAMA Code apply to the promotion and marketing of generic ethical products?

A: Yes, if these products are marketed by PhAMA member companies. Non PhAMA members however are encouraged to voluntarily comply with the PhAMA Code.

Note: This is addressed in Article 1.2 of the Provision of the Code.

3. Disease Awareness Campaigns (↑)

Q: How do we manage the display of the product posters/disease awareness posters once it is handed over to the healthcare professionals?

A: Product Posters/disease awareness posters are to be printed with the wording 'Only for healthcare professionals, to be displayed within the consultation room'.

4. Over-The-Counter Medication Products (↑)

4.1. Q: Are there self-regulatory Codes of practice relating to the promotion of OTC products? Where can I find information on this?
A: Yes, there are self-regulatory Codes of practice on the promotion of OTC products. This is addressed in a separate guidance book covering the promotion of OTC products.
Note: This is addressed in Article 1 of the Provision of the Code.

4.2. Q: Does the PhAMA Code apply to the promotion and marketing of OTC products that may also be prescribed by healthcare professionals?
A: No. The PhAMA Code only applies to the promotion of pharmaceutical products intended to be used on the prescription of, or under the supervision of, a healthcare professional. However, member companies are encouraged to embrace the general principles regarding any interactions with healthcare professionals outlined in the PhAMA Code, irrespective of the kind of the product they are promoting.
Note: This is addressed in Article 1 of the Provision of the Code.

5. Pricing and Terms of Trade (↑)

5.1. Q: Does the PhAMA Code prohibit member companies from giving its customers discounts or other favourable trade terms for the supply of pharmaceutical products?
A: No. The PhAMA Code does not restrain or regulate commercial trade terms for the supply of pharmaceutical products.

5.2. Q: Does the PhAMA Code apply to the promotion and marketing of pharmaceutical products to commercial customers who are also practicing healthcare professionals, such as a pharmacist who operates his/her own practice?
A: The PhAMA Code applies to all interactions with healthcare professionals prescribing and dispensing controlled medicines.

5.3. Q: Does the PhAMA Code apply to the promotion and marketing of pharmaceutical products to commercial customers who are not healthcare professionals? What if the customer is a healthcare professional by qualification but is not practicing?
A: The PhAMA Code applies to interactions with all practicing healthcare professionals. The intention of the Code is to ensure that prescribing and dispensing healthcare professionals are not induced to prescribe/dispense a controlled medicine.

5.4. Q: Does the PhAMA Code cover price lists or other documents describing terms of trade?
A: No.

5.5. Q: Could a false price claim or a misleading price comparison in promotional material be processed under the PhAMA Code?
A: Yes, this is possible when a company is inappropriately using pricing information in its promotional materials or activities.

5.6. Q: Does PhAMA regulate the number of product samples to be provided to each doctor?
A: No. In addition, samples must not be used for unofficial bonus and as an inducement to purchase.

6. Non-Promotional Information (↑)

6.1. Q: What are the examples of non-promotional information that is not covered by the Code?
A: Correspondence, possibly accompanied by material of a non-promotional nature, needed to answer a specific question about a particular medicinal product is not covered by the Code. Non-promotional, general information about companies (such as information directed to investors or to current/prospective employees), including financial data, descriptions of research and development program, and discussion of regulatory developments affecting the company and its products is also not covered by the Code.

6.2. Q: Can promotional claim reference made to data on file as long as it is reproducible upon request?
A: Yes.

7. Disguised Promotion (↑)

7.1. Q: Is it appropriate for a company to publish promotional materials that appear to be independent editorial material?
A: No. Where a company finances or otherwise secures or arranges the publication of promotional material in journals, such promotional material must not resemble independent editorial material.

7.2. Q: Can a company place an advertisement in a lay press/magazine which is intended for circulation among healthcare professionals only?

A: No. A company may not place any advertisement in a lay press/magazine even if it is intended for circulation among healthcare professionals only as there is no guarantee that the magazine would not be placed in a public area.
It is also a concern that such medium/publications which do not contribute to education in terms of healthcare could be a choice for placing such advertisement.
Such advertisement can only be placed in scientific medical journals/publications which are circulated to healthcare professionals only.

7.3. Q: How does the guidance of pre-approval communication and off-label use affect compassionate use programs?
A: The clause does not prevent compassionate use programs which must of course comply with all applicable laws, regulations and Codes. Care should be taken to ensure that communications for a compassionate use program are not, in effect, advertisements for an unlicensed medicine or use.

8. Consistency of Information (↑)

Q: What level of detail is required to be included on labelling, packaging, leaflets, data sheets and all other promotional material in Malaysia?

A: The local guidelines from the Ministry of Health/National Pharmaceutical Control Bureau provide guidance on the minimum information to be included in labelling, packaging, leaflets, datasheets and all promotional materials produced in Malaysia. This should include core product information such as contraindications, warnings, precautions, side effects and dosage.

9. Buntings and Posters at Conferences (↑)

9.1. Q: According to the PhAMA Code, all printed promotional material needs to have an API. Should this extend to buntings and posters that are used in events such as congresses and lunch/dinner talks?
A: Posters and buntings used in events such as congresses and lunch/dinner talks are required to have API. (The term Buntings and posters in this context refers to buntings which includes claims. For buntings & posters which include the brand name & tag line without a claim, this provision does not apply).
The above requirement is clearly stated under Article 5.1 of the PhAMA Code of Conduct, unless the poster is a reminder advertisement, in which case the requirement under Article 5.3 stands.

9.2. Q: Is there any restriction within the Code for display and distribution of branded promotional (Exhibit Booth, brand reminders, brochures with product branding etc.) at Conference in KL?
A: The restriction within the Code for display and distribution of branded promotional material (Exhibit Booth, brand reminders, brochures with product branding etc.) must be strictly adhered to in any event that involves others apart from healthcare professionals, e.g. the public, ministry or industry.

10. Use of Comparisons (↑)

10.1. Q: Does the PhAMA Code allow for comparisons between different products to be included in promotional materials?
A: Yes. Any comparison made between different pharmaceutical products should be based on relevant and comparable aspects of the products and be capable of substantiation. Comparative advertising should not be misleading.

10.2. Q: Can a graph be adapted so that the information of other product which is not used in comparison or of product which has been discontinued from the market be deleted?

A: Yes. If a graph has been adapted from a paper, it must be stated so. A graph can be adapted; provided it is clear and its true meaning is not distorted.

10.3. Q: Can brand names of products of other companies be used as references in CME events without prior consent from the proprietors?
A: No. Prior consent from the respective proprietors must be obtain.

10.4. Q: Can the image of a product without brand name be used as references during CME events without prior consent from the proprietor?
A: Even if no brand names of products of other companies are used, the products' images be it capsules, tablets, or medical devices or as such may be so unique that these items may be identifiable to a particular brand. Thus, prior consent must also be obtained. This has more to do with the Trade Description Act 2011.

10.5. Q: Must the pharmaceutical/samples requested/ordered by healthcare professional in public health institutions be handed over to the healthcare professional concerned?
A: The law does not require that the pharmaceutical/samples be delivered direct to the healthcare professional concerned. It may be handed over to the institution's pharmacy. The public health institutions would have their own internal processes of acquiring samples which mandates signature of the particular healthcare professionals and endorsed accordingly, which may serve as their own internal record. Member companies may however have an even stricter guideline which mandates additional course of actions to be complied to.

11. Article Reprints (↑)

Q: Can companies have article reprints that mention certain names of its products? These reprints are not developed/lead by our company but by an external party. Examples are like Community Based Service articles. Are clinical paper abstracts from publications allowed to be presented at the booth?

A: Such reprints are acceptable to be presented if they are disease education articles only. Any article on promotional/branding prescription product is not allowed.

- Only full text is allowable i.e. publish it as it is.
- Abstracts are not allowed.
- Article reprints are not acceptable.
- Scientific general paper from lay press is acceptable. Those from medical publications i.e. Medical Tribune are not acceptable.

12. Display and Distribution of Branded Promotional Materials (↑)

Q: Is there any restriction within the Code for display and distribution of branded promotional (Exhibit Booth, brand reminders, brochures with product branding etc.) at conferences? (The participants of this conference include stakeholders from Ministries of Health, Finance & Develop; civil society organizations; NGOs; healthcare professionals, media etc.)

A: The restriction within the Code for display and distribution of branded promotional material (Exhibit Booth, brand reminders, brochures with product branding etc.) must be strictly adhered to in any event that involves others apart from healthcare professionals, e.g. the public, ministry or industry.

13. Use of Quotations (↑)

Q: Does the PhAMA Code allow for quotations to be included in promotional materials?

A: Yes. Quotations from medical and scientific literature or from personal communications should be faithfully reproduced (except where adaptation or modification is required in order to comply with

any applicable Codes, in which case it must be clearly stated that the quotation has been adapted and/or modified) and the precise sources identified. Quotations should not change or distort the intended meaning of the author or clinical investigator or the significance of the underlying work or study.

14. Reprints (↑)

14.1. Q: Are reprints considered as promotional material under the PhAMA Code?
A: No. Reprints of scientific and medical articles, when used as stand-alone documents, are not developed by pharmaceutical companies and as such cannot be considered as promotional materials. If, however, they are presented to a healthcare professional together with other, company-originated documents, they then become promotional materials. In all cases, where promotion refers to, includes, or is presented together with scientific or medical articles or studies, clear references should be provided. Any reprint of artwork (including graphs, illustrations, photographs or tables) taken from articles or studies and included or presented with promotional materials should clearly indicate the source of the artwork and be faithfully reproduced.

14.2. Q: Is there any guideline on reprints of data on risk reduction and p-values?
A: Data on risk reduction and p-values needs to be exactly representative of the data shared in the reference literature to ensure there isn't any misunderstanding, misinterpretation and distortion of information.

15. Events Involving Foreign Travel (↑)

15.1. Q: When is it appropriate and justified for a company to organize or sponsor an event for healthcare professionals outside of their home country?
A: No company may organize or sponsor an Event for healthcare professionals that take place outside of Malaysia, where the majority of the attendees are Malaysians. International scientific congresses and symposia that derive participants from different countries are therefore justified.

15.2. Q: What is the percentage considered as majority?
A: 51% and above.

15.3. Q: What is considered as the home country of a healthcare professional?
A: Under the PhAMA Code, the home country of a healthcare professional is referred to as the country in which he/she practices.

15.4. Q: Are speakers/chairpersons bound by the travel class Code which provides for economy class for air travel of less than 6 hours?
A: Yes, this applies to both sponsorships and professional engagements.

16. Appropriate Venue (↑)

16.1. Q: Is the term `venues associated with golf/spa' includes venues which owns and operates the golf course/spa only or as well as venues which have a golf course/spa within its vicinity regardless of whether the golf course is owned/operated by the venue itself?
A: As a rule, venues which directly own/operates golf courses/spa are not acceptable. `Venues associated with golf/spa' may also refer to venues which do not necessarily owns or manages the golf course/spa itself. However, venues which are near/within the vicinity of a golf course/spa may be accepted if there are no other alternative venues within the vicinity which offers the required facilities for the purpose of dissemination of scientific knowledge. It is the onus of the members to better plan their meetings and retain documentations of reasonable justification. Such due diligence should be made available upon request.

16.2. Q: Can a PhAMA member company participate in a medical society's scientific event if it were to be held in luxurious venues?
A: No.

16.3. Q: Can a member utilize a venue which is considered 'inappropriate venue' as it may be the only venue which offers reasonably meeting facilities within the vicinity?
A: As a rule, no. It requires good planning from the members' end to ensure that only venues which are considered appropriate are utilized for their function. It is the onus of the members to better plan their meetings and retain documentations of reasonable justification. Such due diligence should be made available upon request.

16.4. Q: Is it acceptable for members to participate in conferences held at clearly designated conferences facilities like the Sunway Convention Centre or Kuala Lumpur Convention Centre even though they are located within an entertainment surrounding as the venue itself was build and designated for purpose of transfer of knowledge?
A: Yes, it is acceptable to utilize such facilities as such venues are clearly designated conferences facilities.

16.5. Q: Is it acceptable for conference participants to utilize hotel accommodation within the vicinity of the designated conference facilities?
A: Yes. For the purpose of being pragmatic it is acceptable for members to accommodate their participants within the vicinity of designated conferences facilities like Sunway Convention Centre or any other venues, even though they are located within an entertainment surrounding. Members are however asked to exercise restraint and caution in their choice of accommodation to ensure that it can withstand public scrutiny.
*In cases that member companies affiliate companies' overseas sponsors participants to Malaysia to participate in international scientific events held locally and make their own choice of accommodation for their sponsored participants, it is advised that member companies share with their affiliate companies, the PhAMA Code and recommend them a list of hotels which the member themselves would be utilizing for accommodation of their own participants.

16.6. Q: Does PhAMA as a local association has any jurisdiction on the actions and decision of member companies affiliate officers during the latter's participation in scientific events held in Malaysia?
A: No.

16.7. Q: Are participation of member companies at Societies' or Medical Organization's scientific events which includes the AGM component/activities allowed?
A: It would be inevitable for any society or organization to hold their AGM back to back or as part of agenda for CME events to cut costs as well as due to the logistic and time convenience it accords.
As long as the scientific event is at least 75% of the total agenda and that the activities during the AGM do not include unwarranted activities like fun fair, lucky draws, etc. It would be acceptable. Sponsorships provided by member companies should be strictly for scientific event and not for the AGM component/activities.

17. Entertainment (↑)

Q: How should companies interpret the requirement on entertainment in practice?

A: When a company organizes a meeting and refreshments are provided, e.g. an evening meal (for a meeting stretching over more than one day), it would be permitted to provide some background music. However, it would be inappropriate for a company to utilize the entertainment provided at a stand-

alone meeting as a means of attracting healthcare professionals to attend the scientific meeting. Meals and social activities provided must be modest. The 'modest nature' of the entertainment may be interpreted as prohibiting high profile, inappropriate or expensive entertainers - even if their performance is secondary to a necessary meal. So, an appearance by a high profile/renowned local or international personality would not be considered as modest whereas a cultural performance which is offered by the F&B facility as part of the dinner package would be acceptable as entertainment for a meal interlude.

18. Sponsorship (↑)

18.1. Q: Does the provision, `Limited to maximum twice per year/company for each healthcare professional', refers to local sponsorships only or includes overseas sponsorships as well?

A: The phrase ` Limited to maximum twice per year/company for each healthcare professional' refers to international sponsorships only. However, this provision applies only to international event held overseas and not to international events held locally. There are no limits to local sponsorships.

The limit of twice per year for any overseas sponsorship is applicable for sponsorship of a healthcare professional as participants to the event. Any paid for services trips e.g. as chairperson, speaker, etc. or that for clinical research, are not included in the restriction. Kindly take note that sponsorship from either a local representative entity or from the regional body is considered as sponsorship from a same entity.

18.2. Q: Is it acceptable for pharmaceutical companies to request for change of speaker's slot for medical conferences?

A: It is not acceptable. Pharmaceutical companies should not interfere in any proceedings related to independent scientific forums.

19. Fee for Services (↑)

Q: Do members have to follow strictly to the fee for services guideline?

A: Fee for services guideline in the PhAMA Code is based on a concept of fair market value. Whilst the Code provides a cap, it still leaves the jurisdiction to its members to decide on the rate the members see fit.

20. Promotional Aids (↑)

Q: What kinds of items are permissible as promotional aids?

A: Promotional items should be of insignificant and minimal value and should be directly related to the work of the recipient healthcare professional and enhance patient care delivery. Possible examples include pens, notepads and surgical gloves. Promotional items intended for the personal benefit of the healthcare professional, such as music CDs, paintings or hampers would not be acceptable.

21. Items of Medical Utility (↑)

21.1. Q: What kinds of items are envisaged as being items of medical utility?

A: Items of medical utility may be offered or provided, provided that such items are of modest value, do not exceed RM500.00 and are beneficial to the provision of medical services and for patient care. For medical educational material, e.g. journals, textbook & anatomy models, the limit is up to RM1,000.00/institution. Items should not be offered on more than an occasional basis, even if each individual item is appropriate.

21.2. Q: Is it acceptable to print/put the company's logo on any educational materials or items of medical utility?

A: It is acceptable to print/put the company's logo on any educational materials or items of medical utility. Brand names are however not allowed.

22. Sponsorships (↑)

22.1. Q: Is the support of a medical society or hospital social event - annual general meeting, annual dinner, family day - in the form of donation and/or gifts allowed by the PhAMA Code?
A: This is not allowed.

22.2. Q: It is mentioned that 'limited' entertainment is acceptable and should be modest and secondary to the main purpose of the meeting. If the company pays for a half or full-day city tour for their sponsored doctors &/pharmacists, is this acceptable?
A: Company should not organize any sightseeing activities or other holidaying, leisure and sporting activities even if 75% of the time in the meeting involved is dedicated to scientific and educational contents.

22.3. Q: Is the support of charitable events organized by health societies where the contributions benefits patients allowed by the PhAMA Code?
A: Yes, this is allowed.

23. Gifts (↑)

23.1. Q: Does PhAMA allow for infrequent Cultural Courtesy for local customs?
A: Yes, it is allowed and may be given not more than twice per year to a healthcare professional in acknowledgement of significant festive occasion.

23.2. Q: Is purchase for a congratulatory flowers/wreath limited to RM100.00?
A: Congratulatory flowers are not allowed because it is considered a personal gift. Bereavement wreath is not covered under the provision of the Code. Please refer to your own company policy.

23.3. Q: Is a thumb drive considered a personal gift or something which is relevant to the practice of medicine or pharmacy?
A: This is acceptable as long as the item is less than RM100.00.

23.4. Q: Can inexpensive food items and drinks as per social/cultural norm may be provided to HCPs during the course of day to day promotional activities?
A: Yes.

23.5. Q: Can food items with the company's name or product name be given out to healthcare professionals?
A: No.

23.6. Q: Can the industry provide healthcare professionals with rubber stamps of the generic name of a product with its accompanying prescription requirement?
A: There in no issue with the industry providing rubber stamps of the generic name of a product and its corresponding prescription requirement. Furthermore, the rubber stamp is for the use of healthcare professionals only.

24. Payment of Honoraria to Speakers (↑)

24.1. Q: Is the payment of honoraria to speakers allowed by the PhAMA Code?
A: The PhAMA Code does not encourage the payment of honoraria to local speakers. The payment of reasonable expenses such as cost of air travel, meals and lodging may be provided to healthcare professionals. If an honorarium is paid, the fair market value of the services provided is RM1,500.00/engagement/day with up to maximum RM3,000.00/multiple engagement/day with a detailed signed contract on the services, for auditing purposes and proof that it is not an inducement, is required. For events held

outside Malaysia or at international events held in Malaysia, kindly refer to the member companies' internal guidelines. The same proposal on a signed contract remains.

24.2. Q: What is the rate for payment of honoraria to Malaysian speakers at local/international events?

A: Kindly refer to the following:

24.2.1. Malaysian speaker in a local event:

If an honorarium is paid, the fair market value of the services provided is RM1,500.00/engagement/day with up to maximum RM3,000.00/multiple engagement/day with a detailed signed contract on the services, for auditing purposes and proof that it is not an inducement, is required.

24.2.2. A Malaysian speaker in an international event but held locally in Malaysia:

Companies should follow each internal company Code guidelines.

24.2.3. A Malaysian speaker in an international event, outside Malaysia:

Companies should follow each internal company Code guidelines.

24.3. Q: What is the rate for payment of honoraria to chairperson?

A: The term 'speaker' in Article 7.4 covers the 'chairperson' as well. As such, the rate for payment of honoraria to local HCPs chairing local meetings is the same as payment of honoraria to local speakers at local events.

25. Others (↑)

Q: Can the Plaintiff and Defendant be represented at the Ethics Case Review Committee meeting?

A: The Plaintiff and Defendant will be called for representation at the Ethics Case Review Committee meeting. No external legal counsel is allowed.

26. Medical devices (↑)

Q: Do medical devices that accompany a product come under the purview of the PhAMA Code of Conduct?

A: Yes. A medical device that accompanies a product comes under the purview of the PhAMA Code of Conduct. A refrigerator is not a medical device.

27. In-Vitro Studies (↑)

Q: Are claims derived from in vitro studies (e.g. human lung tissue) acceptable?

A: In-vitro, laboratory or animal data alone are not sufficient to substantiate a clinical claim.

Glossary: PhAMA Sponsorship and Congresses (↑)

1. ### Conducive to Educational Objectives
   Scientific and educational meetings supported by pharmaceutical companies must take place in an environment that is suitable for learning. Distractions could detract from a suitable environment.
2. ### Congress
   National or international meeting with the presentation of scientific papers, posters etc. Congresses usually cover a specific area of medicine and are commonly run by a medical society.
3. ### Cultural Events and Attractions
   Events or local attractions which are non-scientific or not directly related to the scientific purpose of the meeting. These include sporting or artistic events and attractions, historic and other touristic sights, inclusion of singing, dancing or other entertainment in the proceedings.
4. ### Easily Accessible
   Avoiding long, difficult or expensive journeys for participants. A remote location may have been chosen for touristic attractiveness.
5. ### Entertainment
   Non-scientific activities that go beyond the necessities of running a scientific meeting such as sightseeing tours, musical or theatrical performances or leisure activities.
6. ### Event
   A broad term covering gatherings of several healthcare professionals and others. It includes congresses, symposia, meetings etc. and may involve from just a few to many thousand participants.
7. ### Grant
   The provision of financial support.
8. ### Healthcare Professionals
   Defined in the IFPMA Code as" 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." National Codes may adapt the definition because of local legislation or to accommodate local roles and practices in healthcare.
9. ### Hiring of Exhibition Space
   Payment for the facility to exhibit promotional or non-promotional material or provide other services at an event. Commonly this involves hiring floor space in an exhibition hall where a company booth is erected on which company material is displayed and distributed. Modest refreshments are also sometimes provided.
10. ### Hospitality
    Food, drink and accommodation
11. ### International Meeting
    A meeting that involves delegates from several countries. It may be regional or world-wide. A truly international meeting actively seeks and receives delegates from several countries. A meeting with the large majority of delegates from one country is unlikely to be considered as truly international.
12. ### Lavish
    An impression of luxury, opulence or extravagance irrespective of the actual price paid.

13. Location

    The geographical place where a meeting is held.

14. Medical Education

    Includes 'Continuing Medical Education'. The wide range of activities which medics and other health professionals must undertake to ensure that their medical knowledge is adequate and kept current for their responsibilities. Activities include meetings, congresses, on-line training, courses, preceptorships etc. These may be organized by various bodies such as medical societies, academic institutions, healthcare organizations, specialist companies and pharmaceutical companies. Various accreditation schemes for medical education activities exist in different countries and for different medical specialties. Continuing Professional Development is similar but incorporates development areas beyond medical matters.

15. Meeting

    An organized assembly of people for a particular purpose including formal discussion.

16. Modest

    Not extravagant in impression or actual cost. National Codes and company policies may give guidance on what is likely to be considered as modest e.g. by quoting monetary limits or through case reports.

17. Note for Guidance (NfG)

    A commentary that is designed to help in the interpretation of official IFPMA documents such as the Code of Practice. It is intended to explain the thinking and background to requirements but does not itself constitute 'official' requirements.

18. Provision of Speakers

    Enabling speakers to attend and present at events by covering travel, accommodation and hospitality costs. In addition, a fee for service may also be paid. A contract will describe the arrangements.

19. Recognized Scientific or Business Centre

    A location which is known for its facilities that enable scientific or business activities and discussion.

20. Satellite Symposium

    A symposium that does not form part of the main proceedings of a congress but is nevertheless is subject to rules and criteria set by the congress organizers and is mentioned in the official congress literature. A symposium that has no official link with the congress but happens to be taking place nearby at about the same time would not be considered a satellite symposium.

21. Scientific and Educational Content

    Presentations, discussions, posters, electronic material and other content that is primarily related to science, medicine and the professional development of healthcare professionals and others.

22. Social Program

    Parts of an event program that are not directly related to the scientific program. These include cultural events and attractions, pre- and post-meeting tourism opportunities, accompanying persons' programs etc.

23. Sponsorship

    Providing monetary or other support for an event. This includes direct grants to the organizers, hiring exhibition space, payments for other services and activities connected with the event or otherwise supporting the event through a transfer of value.

24. Sponsorship of Attendance

    Providing monetary and other support that enables, in whole or in part, delegates to attend an event. It includes supporting travel costs and arrangements, hospitality, registration fees etc.

25. ### Supporting Meetings

    Sponsorship of events, sponsorship of attendance, provision of speakers and other transfers of value associated with an event.

26. ### Third Party Event Organizers

    Parties such as companies, associations, societies and individuals who organize 'events' i.e. organizers other than pharmaceutical companies.

27. ### Venue

    The building where the event takes place. Usually venues are conference centres, business hotels, hospital training centres or other business or medical facilities.

History of PhAMA Code of Pharmaceutical Marketing Practices (↑)

1.	First Edition	1978
2.	Second Edition	1981
3.	Third Edition	1991
4.	Fourth Edition	1994
5.	Fifth Edition	1995
6.	Sixth Edition	1999
7.	Seventh Edition	2001
8.	Eight Edition	2002
9.	Ninth Edition	2004
10.	Tenth Edition	2005
11.	Eleventh Edition	2005
12.	Twelve Edition	2006
13.	Thirteen Edition	2007
14.	Fourteenth Edition	2008
15.	Fifteenth Edition	2008
16.	Sixteenth Edition	2008
17.	Seventeenth Edition	2009
18.	Eighteenth Edition	2010
19.	Nineteenth Edition	2012
20.	Nineteenth Edition (updated version 1)	2015
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