2024

PhAMA Code of Practice

For Prescription (Ethical) Products – Edition 22.1

Pharmaceutical Association of Malaysia

Contents

Introduction (↑)

The PhAMA Code of Pharmaceutical Marketing Practices was first drawn up and adopted by the members in 1978. It undergoes constant reviews by the association and has been amended and updated from time to time where necessary.

Notwithstanding any provision made under the Code, all 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 Mechanism, which sets time frames for the processing of 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.

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

Therefore, the major sanction against any company that transgresses the Code is 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 standards of conduct and professionalism in the marketing of pharmaceutical products.

There are obvious difficulties in drawing up exacting standards 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 and the medical and allied professionals. Self-discipline and restraints are an integral part of the Code, which must be applied not only in spirit but also 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 products, either Group `B' or Group `C', or biological product (irrespective of patent status and/or whether it is branded or not) which is intended to be used via prescription, or under the supervision of a healthcare professional, and which is intended for use in the diagnosis, treatment or prevention of human diseases, 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 comprises healthcare professionals that provides healthcare or conducts healthcare research.
- "company" means any company that is a PhAMA member.

1.3. Exclusions

This Code does not regulate the following activities:

- Promotion of self-medication products that are provided "over the counter".
- 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.
- Public Disease Awareness Campaigns. (Any mention is for purpose of providing clarity only).

2. General Principles (↑)

2.1. The Healthcare and Well-Being of Patients are Top Priority for Pharmaceutical Companies.

2.2. Methods of Promotion

Methods of promotion or marketing must never be such as to incite unfavourable comments or 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 doing 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 programs 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 use (whether promotion in nature or otherwise) which is sponsored by a company should clearly indicate who is the sponsor.

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 obtained.

This provision is not intended to prevent the right of the scientific community and public to be fully informed on scientific and medical progress. It is not intended to restrict a full and proper exchange of scientific information of 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. Notwithstanding any disclaimer that a product is not approved in the country, only generic name of the product should be used. Brand name of the product can be used only be used in the instance where the product is registered in the host country and the event is confined to physical meeting.

Only Medical/regulatory functions of our member companies will respond to unsolicited queries pertaining unapproved or off-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, promotional 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 in published data to which references are given. It must not state that a product has no side effects, toxic hazards or risk of addiction. The word "safe" must not be used.

The word "new" should not be used to describe any product or presentation that is generally available, or any therapeutic indication for which the product/ indication has been registered in Malaysia for over 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 such claimsare not presented in a way which is likely to mislead, whether by distortion, undue emphasis or otherwise.

Similarly, the clinical and scientific opinions of medical and allied professionals should not be disparaged either directly or by implication.

5. Printed Promotional Materials (↑)

5.1. All Printed Promotional Materials, 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 official marketing agent;
- date of advertisement; and
- "Prescribing information" (PI) &/or "abbreviated prescribing information" (API) should include an approved indication together with the dosage and method of use; and a succinct statement of the contraindications, precautions and side effects. Companies can opt to have the latest PI &/or API accessible via QR code or any other digital link/apps of choice. Each QR Code or any other digital link must reflect the most current PI or API information for reference purposes.

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

5.2. All Printed Promotional Materials, Other Than Those Covered in Article 5.3 Below,Should Also Fulfil the Following Requirements:

- Promotional materials such as mailers, journal advertisements and loose inserts must not be designed to disguise its real nature.
- Advertisements in journals should not be designed to resemble editorial material.
- Promotional materials should conform, both in text and illustration, to canons of good taste and should recognize the professional standing of the recipient.
- All printed promotional materials should include the name of the product (normally the brand name), generic name of the product and date of advertisement.
- Doctors' names or photographs must not be used in a prominent manner in promotional materials or in any way that will contravene the ethical Codes of the medical profession.

- Promotional materials should not imitate the devices, copy, slogans or general layoutadopted 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 materials.
- Disclaimer statement "For Healthcare Professionals only" to be added to printed materials with HCP as target audience.

5.3. Reminder Advertisements

A "reminder" advertisement is defined as a short advertisement containing only 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" as referred in Article 5.1 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 a clear, fair, balanced view and should only be included if they are relevant to the claims or comparisons being made.

Graph and tables must not be used in misleading manner, such as being incomplete, by suppressing zeros or presenting unusual scales.

Graphs that are adapted from a paper must state 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

Materials 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 highlighting or underlining selected portions for prominence)

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 Materials

Promotional materials should only be sent or distributed to 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 Healthcare Professionals (HCP).

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

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

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

Specifically, in the case of pharmaceuticals product-related websites:

- the identity of the pharmaceutical company and intended audience should be apparent;
- the content should be appropriate for the intended audience;
- the presentation (content, links, etc.) should be appropriate and apparent to theintended audience;
- the company concerned obtains consent or permission from the recipient before sharing promotional materials;
- 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. annualgeneral 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 if majority of the attendees are practicing in Malaysia. However, international scientific congresses and symposia with participants from different countries are justified and permitted to be hosted in any country represented by the delegate. (All sponsorships and meeting criteria still apply).

7.1.3. Dissemination of Information for Unapproved Products or Indications

7.1.3.1. Local Meetings inclusive of CMEs

Dissemination of scientific information for a pharmaceutical product or indication that has not been approved for marketing by the Drug ControlAuthority (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-basedCME committee.
- Based on verifiable (e.g. poster/ abstract/publication) data or peerreviewed reprints as a CME event endorsed by a professional body.
- Relevant permission from authorised bodies (if required).

7.1.3.2. International Meetings

Information at International meetings / Symposia / Congress heldin Malaysia that appear on exhibition stands or is distributed to participants may refer to pharmaceutical products that are not registered in Malaysia, or which are registered under different conditions, with the following conditions:

- 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 clear statement indicating that the product/indications/dosage form is not registered and 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 may 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 purpose of the Event or meeting.

Companies should not organize Events nor provide financial support including sponsoring HCPs to any event at renowned venues not appropriate for the purpose of scientific education or 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 ofattendees/good internet access)
- located to minimise travel for attendees
- have adequate security
- able to withstand public and professional scrutiny

7.1.5. Limits

7.1.5. Meal Limits

Meals and/or refreshments provided to HCPs during business meetings and incidental to events (scientific meetings or conferences that are included in the meeting package) must adopt a risk-based and principles-based approach as meals are secondary to the interaction. PhAMA encourages members to set their own internal guidance.

Meals and/or refreshments can be provided

- if they are modest and reasonable by local standards;
- As per internal guidance on value/limits of individual companies.

7.1.6. Entertainment

No entertainment, 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 meetings.

Games must not include elements of chance or a mix of elements of chance.

For 3rd party educational events where lotteries or lucky draws are present:

- Member companies should not be involve in the planning and execution of lotteries/lucky draws activities, except for verifying booth attendance.
- Member companies should not sponsor gifts for the lotteries/lucky draws.
- Members must clarify or detail the sponsorship component to ensure that it does not include any aspect of lotteries/lucky draws.

7.2. Sponsorships

Member companies may sponsor healthcare professionals to attend External International

Events/meetings provided:

- The Event complies with the requirements in this Code as described in Article 7.1;
- Sponsorship is limited to the payment for travel, meals,accommodation and registration fees;
- Only cover basic economy travel (for travel time below 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;
- Sponsorship 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. Honorarium

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 andparticipation at advisory board meetings where remuneration is required. The arrangements which cover these genuine consultancies or other services must fulfil 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;
- 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 necessary expertise;
- The number of consultants must not be greater than the number reasonably necessary to achieve the identified need;
- The hiring of the consultant for the relevant service must not be an inducement to prescribe, recommend, purchase, supply, and/or administer any medicine;
- The fair market value of the services provided is up to **max** of RM2,000/role/engagement with up to **max** of RM4,000/multiple roles/engagement. The honorarium covers pre-preparation work, which covers but is not limited to pre-reads, slide decks and video recordings.
- For healthcare providers appointed to be on an Advisory Board, the same honorarium applies.
- For local speakers at international events held locally or outside Malaysia, members are advised to refer to their own company's internal Code. The need for a signed contract remains.
- For international speakers, members are advised to check with the speaker's home country Code and apply accordingly. The need for a signed contract remains.

7.5. Marketing Research

7.5.1. Methods Employed

Methods employed for marketing research must not bring discredit upon or reduce confidence in the pharmaceutical industry. This provision applies whether the research is carried out directly by the company concerned or 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

Incentives offered to informants should be minimised and commensurate with the amount of 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 kept confidential, unless specifically agreed otherwise.

(In the absence of this agreement, 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

Gifts, where permissible, must never constitute an inducement to prescribe, recommend, purchase, supply, sell or administer a pharmaceutical product.

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

7.6.1. Prohibition of Cash and Personal Gifts

Gifts for the personal benefit (such as sporting or entertainment tickets, electronic items, social courtesy gifts, etc) of HCPs (either directly or through clinics and institutions) are prohibited. Providing or offering cash, cash equivalents or personal services are also prohibited. Personal services are defined as any service unrelated to the HCP's profession and that confer a personal benefit to the HCP.

7.6.2. Promotional Aids

A promotional aid is a non-monetary item given for a promotional purpose (which does not include promotional materials as defined in Article 5 & 6). Providing or offering them to HCPs for the promotion of prescription-only medicines is prohibited. Examples of banned promotional aids include sticky notes, mouse pads, calendars,

etc.

Pens and notepads can be provided to HCPs for company events or third-party scientific events for the purpose of note-taking. They must not bear the name of any medicine, campaign names, tag lines and logos of therapeutic areas but may carry the company name.In addition, they must be of minimal value (below RM15 nett per item) and only the necessary quantity is distributed.

(Pens, notepads or other items considered as promotional aids or gifts are not allowed for distribution during booth exhibitions).

Thumb drives are allowed if the purpose is to store the information to be provided to the HCP. The size of the thumb drive must be relevant to the size of information provided.
This code does not govern promotional aids for Over The Counter products.

7.6.3. Informational or Educational Materials or Items of Medical Utility

7.6.3.1 Educational Items that enhance Patient Care

- **Informational or educational items for HCPS**

Informational or educational items may be provided to HCPs for their education provided they are primarily for educational purposes and do not have independent value.

The items provided are of direct educational value, have no promotional value and should be offered only occasionally.

The value of medical educational material to institutions or HCPs e.g journals, textbook, anatomy models and subscription must not exceed RM1,500/year/per institution or HCP.

It is acceptable to print/place the company's logo on educational materials. Product branding, product campaign names, taglines and logos of therapeutic areas are not allowed.

- **Informational or educational items for patients on disease and treatment methods**

Items to educate patients on disease and treatments may be offered by member companies provided that the items are primarily for educational purposes and do not have independent value.

These items can include the company name, but not the product brand name, unless it is essential for the correct use of the item by the patient.

7.6.3.2 **Items of Medical Utility to enhance the Provision of Medical Services and Patient Care**

Items of medical utility may be provided by member companies if they are of modest value, do not exceed RM500/item/HCP, do not offset routine business expenses and help enhance the provision of medical services and patient care. They should be offered only occasionally.

Examples of routine business expenses include stethoscopes, surgical gloves, blood pressure monitors, and needles that are expected to be supplied by the HCPs themselves or their employers.

It is acceptable to print/place the company's logo on educational materials. Product branding, product campaign names, tag lines and logos of therapeutic areas are not allowed.

7.6.4. Cultural Courtesy

Gifts of cultural courtesy are not allowed. (Please refer to article 7.6)

7.6.5 Definition of 'gifts' (hadiah) under 'Garispanduan Pengendalian Medicine Access Scheme untuk Fasiliti KKM' published by Pharmacy Services Program (PSP), MOH

In March 2023, PSP released the new Guidelines for Management of Medicine Access Schemes in Public Health Facilities. The guidelines serve to enhance governance and transparency of medications provided on complimentary basis to government hospitals and clinics.

This encompasses Patient Access Schemes, Patient Assisted Programmes -Special Approval (PAPSA) and Samples. (https://www.pharmacy.gov.my/v2/en/documents/garis-panduan-pengendalian-medicines-access-scheme-masc-fasiliti-kkm.html).

Under the new guidelines (Pg 6, PAPSA dan *Ubat Sampel*), all sample products (including PAPSA and Samples) are now defined as '*Hadiah'* or gift. PSP has specified that this terminology is only applicable to government facilities for documentation purposes, and should not be a deterrent to pharmaceutical companies in providing access to the medications required by patients.

As such, the normal understanding of 'gift' does not apply in the conducting of PAPSA and sample products for member companies. (*Refer Addendum on MASc- Page 45*)

8. Samples (↑)

8.1. Product samples should be no larger than the smallest commercial pack ofeach strength and clearly labelled as "Samples – Not for Sale" or similar wording allowed by law.

8.2. Where products are restricted by law to be distributed by a representative upon prescription, the sample must be handed directly to the doctor or a personauthorised 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 securely to avoid 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, and should be used 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 monitor the samples whilst they are in the possession of medical representatives. If the Member Companyis aware of sample misuse, they have the right to discontinue sample distribution.

8.6 Definition of 'Samples' as 'Hadiah' (gifts) under 'Garispanduan Pengendalian Medicine Access Scheme untuk Fasiliti KKM' (*Refer to Addendum on Page 45).*

9. Clinical Research and Transparency (↑)

9.1. Transparency

Companies are committed to the transparency of clinical trials which they sponsor. There are important public health benefits in 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 medical 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. Therefore, financial support from member companies is appropriate.

Content for CME activities and programs 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 will contribute to enhancing patient care.

On a professional basis, a doctor or pharmacist employed by a member company is allowed to attend Scientific meetings organized by a competitor's company under the umbrella of a professional Society or Organisation of which he is a member (e.g. MMA, MPS).

11. Grants & Donations (↑)

Donations are for charitable purposes and non-profit organisations.

Grants are provided to support educational programmes (including but not limited to requeststo 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 overheads (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 involvement are clear from the start. Companies cannot request to 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 written documentation stating the nature of support,

including the purpose of the activity and scope of funding.

12.4. Events

Companies may provide financial support for patient organization meetingsprovided that the primary purpose of the meeting is professional, educational, and scientific in nature, or supports the mission of the patient organization. Meetings for patient organizations must be held in a venue that is appropriate and conducive to informational communication. Meals or refreshments provided must be modest by local standards.

12.5. Disease Awareness

12.5.1 Disease Awareness Campaigns for the Public

The Code does not govern Disease Awareness Campaigns for the Public. Member companies may undertake these Campaigns on their own or provide support, sponsor or partner with appropriate medical associations, as long as they comply with local laws, regulations, and/or codes.

Disease awareness campaigns should not be misused as disguised promotions. Disease education activities may provide information, promote awareness and educate the 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 or product brands.
c) The activity should focus on the condition and recognition of symptoms rather than treatment options.
d) Disease management options should be presented in a comprehensive, balanced and fair manner.
e) Companies must ensure that the venue is appropriate andconducive to informational communication.
f) Only the company logo is allowed in items or materials involved in such campaigns. Campaign names, taglines and logos of therapeutic areas are not allowed.

12.5.2 Disease awareness campaigns to HCPs

Disease awareness campaigns to HCPs must not involve items of independent value/promotional items/reminders. However, refreshments of not more than RM40/per person (for a drink and one food item) can be distributed to HCPs for disease awareness blitz. Company branding, product branding and tag lines are not allowed on food and beverage items.

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

13.1. Requests from individuals 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 materials issued for distribution or display at locations accessible to the public must not include messages likely to induce a demand for any Scheduled Poison.

13.3. Patient education leaflets on disease conditions must be fair, unbiased, not contain product names. Reference to the company providing the leaflet is restricted to its name and 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 healthcare professional.

13.5. Use of Social Media Communication

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

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

Information including:

- A product name/logo (either branded 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.
- 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 should be supported with referencing, scientific disclosure,conflict of interest and privacy statements.

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.

14.2. Medical Representatives

- Medical representatives must be adequately trained, with 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 familiar with the Code and stay updated with the latest editions.
- 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, or offer payment/ fees to gain an appointment.
- A company will assume responsibility for correcting breaches of the Code resulting from misconduct or misrepresentation of facts by any representative.
- The system of remuneration for representatives should not adversely influence the proper prescription and usage of pharmaceutical products.

(The provision relating to remuneration is intended to ensure there are no incentives 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. Alternatively, a senior company employee(s) can 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 related 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 outlined in Appendix 1: Operation of The Code.

15.2. Measures to Ensure and Enforce Compliance

Member companies are strongly encouraged to adopt procedures that ensure adherence to the PhAMA Code of Practice. 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 for compliance with the Code.

16. Valid Patent Rights (↑)

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

Appendix A (↑)

Operation of The Code

1. Any complainant company should first initiate contact with the company alleged to be in breach to discuss the issue and endeavour to settle the dispute / disagreement of any subject matter, prior to submitting a written complaint to the Ethics Committee for deliberation.

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

   (This is to encourage companies to communicate and attempt to amicably settle any issues. Often, CEOs are not aware of such complaints. CEOs should be responsible for activities within their respective companies.)

   Every case shall be treated as a new complaint. However, in the event of repeat breaches, the Ethics Committee has the right under the PhAMA Code of Practice to proceed without insisting on prior communication between two parties.

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

   A penalty of up to RM100,000 will be meted out to repeat offenders.

   In cases of repeated breaches of the same section/s of the PhAMA Code of 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's company (to ensure the CEO of the company is aware that a complaint has been submitted) together with an administrative fee of RM3,000 to PhAMA. The administrative fee cannot be used to offset thefine. 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 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, the name of the product and products involved.
   - The company of 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, it needs to be reported by or confirmed by an independent witness if there is no documented proof.

2. The Ethics Committee shall meet soonest upon receipt of the complaint from the Secretariat to decide if there is a case for the subject company to answer.
3. In the event the Ethics Committee decides 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 case must be submitted in 20 copies.

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

   The Plaintiff and Defendant will be called to the Ethics 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, the Defendant & Plaintiff may offer 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. The offending text must not 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 Committee and the Ethics Appeal Committee. It suffices for the decisions to be e-mailed to the Board priorto 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.

   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 the formal notice of the Committee's decisions, after which the party concerned loses the right to appeal.

   The appeals fee is RM3,000. The complainant does not have the right to appeal if 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 by the defendant within 2 weeks, the complainant's administrative fee of RM3,000 will be refunded/forfeited depending on the Committee's findings. If found to be in breach, the defendant will be fined up to RM50,000 or RM100,000*. (See Appendix B)

6. If the defendant is found not guilty, the complainant's administrative fee of RM3,000 will also be forfeited.

   If the defendant company wishes to appeal against the Committee's decision, the appeal should be submitted with an administrative fee of RM3,000 to the Secretariat within 2 weeks of receipt of the decision. The company must also discontinue the offending material/practice/text and it should not be reproduced in any other media(See Article 3 above) pending a decision on the appeal. (The administrative fee of RM3,000 goes to the cost of external 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 fees will be borne by the appellant. (Appendix C provides the process flow chart of the Ethics Appeal Committee).

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

8. In the event the Ethics Appeal Committee decides 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 withdrawthe 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 will be forfeited, while the complainant's administrative fee of RM3,000 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 will be refunded to the subject company, while the complainant company's administrative fee of RM 3,000 will be forfeited.

9. If there is no reply 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 no 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 there is no indication of the withdrawal of the material or discontinuance of the practice is received by the set deadline, the Board of Directors may:

- Notify IFPMA** of 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 personor 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. Every member shall be bound by the Board of Director's decision in matters relating to his rights, obligations, duties and privileges as a member of the Association. If a member resorts to court proceedings in respect of his rights, obligations, duties and privileges or on behalf of any other members or in respect of the rendering or meaning of the provisions of this Constitution without first referring to the Board of Directors or in violation of any decision or directive of the Board of Directors, he shall also cease to be a member of the Association and shall not be entitled to exercise any rights of a member.

15. Procedure Review for 3rd party complaints
    15.1. Complaints by a third party would be dealt with in a similar procedure to a member company's 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 complained is not a PhAMA member, PhAMA will revert to the complainant and request that it lodge a complaint with the relevant trade association.
    15.4. On receiving the complaint against a PhAMA member company, 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 concerned have communicated but were unable to come to a decision, the complaint comes back to the Ethics 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 appeal fee.

* In cases of repeated breaches of the same section or sections of the PhAMA Code of Practice 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 Committee - Case Review: Normal Case

Role	Position	No
Chairman	Board of Director	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 seek the advise of DCA/MAB to enforce its decision.
3. A heavier penalty of up to RM100,000 will be meted out in cases of repeat breaches of the same clause or clauses of the Code of Practice.
4. Committee members who are not a Medical doctor or 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	Board of Director	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 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 an attempt 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 notify the defendant that it intends to do so after 14 working days from the date of the defendant's receipt ofthe 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 complaint document. The document will be evaluated to ensure that the complaint logged is within the ambit of the PhAMA Code of Practice and thus within the jurisdiction of the Ethics Committee.

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 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 the Chairperson and those who may form a case review panel.

PhAMA may invite two 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 they require more time and/or information before deliberating on the case further. Another case review panel meeting may be held thereafter.

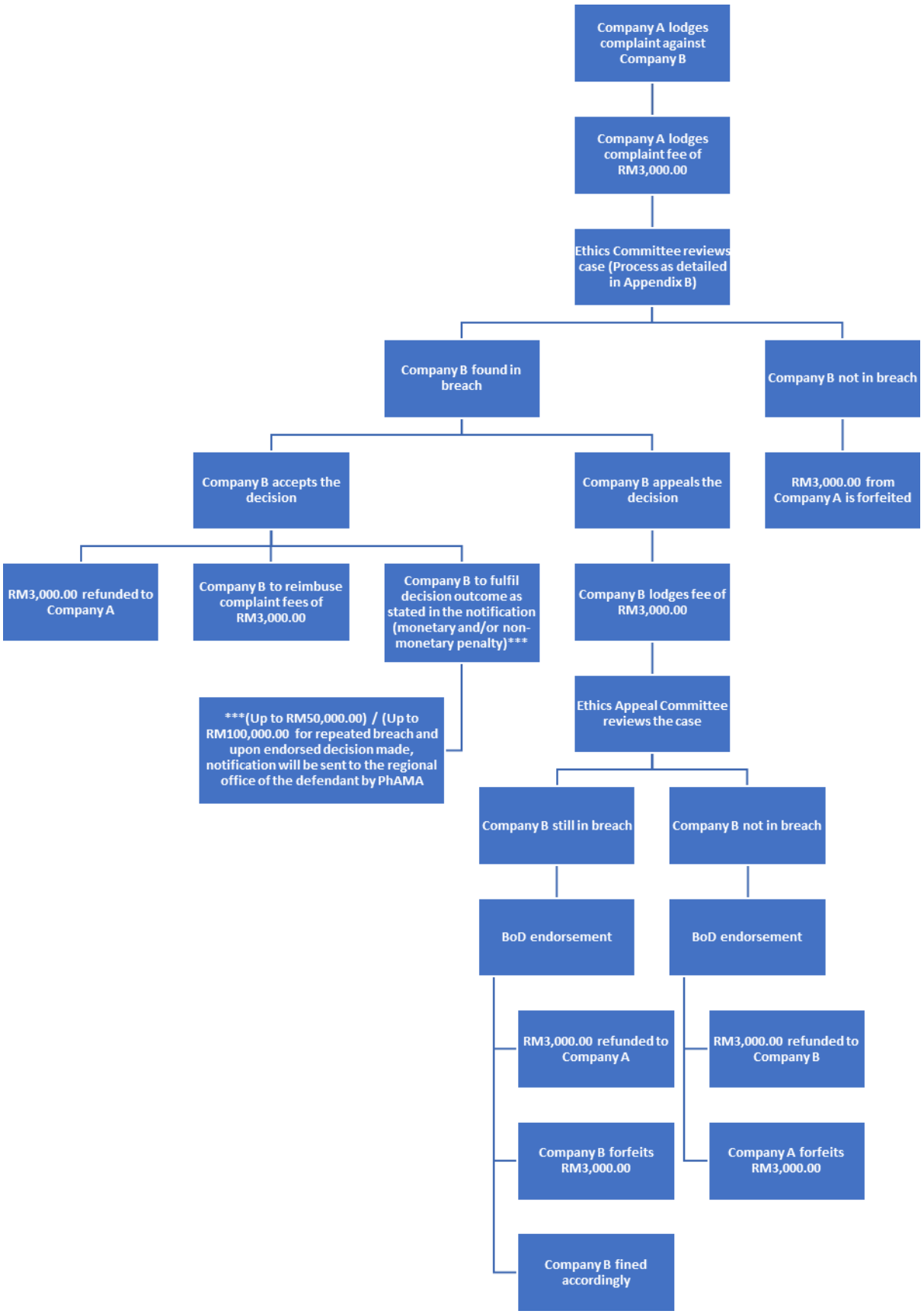
4. Post Ethics Case Review Panel Session

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 requires the panel to seek 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's decision.

Summary of Ethics Review Process



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 continues to evolve, it has already demonstrated its remarkable ability to inform and educate global audiences on a wide range of subjects including healthcare 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 to provide accurate and scientifically reliable information on medicines in a responsible manner to benefit 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 and self-auditing through the implementation of the Code of Practice, which governs marketing and promotional practices. PhAMA believes that self-regulation is a preferred choice for controllingthe type and quality of information on pharmaceutical products provided by pharmaceutical companies via the Internet.
- Wherever they market their products, pharmaceutical companies who are members 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. These requirements are equally valid for and applicable to information made availablevia the Internet.

Sale and Supply via The Internet

- PhAMA/IFPMA shares concerns that the Internet can be misused by unscrupulous parties to bypass normal controls and sell prescription medicines directly to patients without appropriate professional consultation. Patients' health may be put at risk by such practices. The industry supports measures to prevent such activities and educate consumers about the dangers of procuring medicines 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 risk 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. Regulationand enforcement activities by the government should, therefore, focus on the physicalmovement 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 provided only 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 challenges presented by the global dimensions of the information available on the Internet but believe that they can provide opportunitiesfor constructive change that prioritises the interests of the patient/consumer.

- 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. The evolution of the Internet has brought sharpened the need for greater harmonisation. Greater uniformity in 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. Direct promotion to the public, patient organization, medical institution is allowed, covered by local laws, regulations and/or relevant Codes of Practice. Member companies should 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 Practice even if the advertisement is not in the spirit of the Code?

A: The Ethics Committee reviews and deliberates each case based on its merits irrespective of MAB's approval. Complaints should be forwarded to the Ethics Case Review Committee, via the normal complaint process.

2. Generic Ethical Products (↑)

2.1 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/ Promotional Blitz(↑)

3.1 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'.

3.2 Q**:** Is hospitality to HCPs during promotional blitz allowed? The PhAMA Code states that F&B can be given during disease awareness blitz.

A: No. Hospitality/Meals are not allowed to be distributed to HCPs during promotional blitz.

3.3 Q: Are screening vouchers for patients, given through HCPs considered as gifts or inducement to the doctors? Screening vouchers have independent value.

A: Screening vouchers for patients, given through HCPs, are not considered as gifts or inducement to the doctors provided that it is not targeted to specific doctors in the particular therapeutic area nor patients.

From a Code perspective, such distribution is not allowed if it is targeted to a specific group of HCPs in the therapeutic area.

Furthermore, even though screening vouchers may have independent value, it does not have transferable value.

PhAMA supports disease awareness activities as screening is one of the means to encourage early diagnosis of disease and enhance public health.

3.4 Q: Is there any guidance on the number of screening vouchers that can be distributed in disease awareness campaigns?

A: The cost of screening differs from one disease to another. As such, the Committee leaves the decision on the number of vouchers to be distributed during a disease awareness campaign to the discretion of the company concerned.

3.5 Q: Can glucometers or as such be given away to patients through HCPs in a disease awareness campaign?

A: No. Glucometers is considered as an item with independent value an d transferable value (i.e. can be exchanged with money). Furthermore, such items would be given to those who are already diagnosed as patients by the HCPs and thus may be considered as targeted patients.

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

4.1. Q: Is there a Code of Practice relating to the promotion of OTC products? Where can I find information on this?

A: Yes, there is a Code of Practice on OTC products 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 be prescribed by healthcare professionals?

A: No. The PhAMA Code only applies to the promotion of pharmaceutical products intended to be used in the prescription of, or under the supervision of, a healthcareprofessional. However, member companies are encouraged to embrace the general principles regarding 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: Can 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 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 advertisements in a lay press/magazine even if it is intended for circulation among healthcare professionals only, as there is no guarantee the magazine may show up in a public area.
There is also concern that such medium/publications which do not contribute to healthcare education could be a choice for placing such advertisements.
Such advertisements 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 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 (↑)

8.1 Q: What details are required on labelling, packaging, leaflets, data sheets and all other promotional materials 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 arerequired to have API. (The buntings and posters in this context refer to buntings which include claims. This provision does not apply to buntings and posters which include the brand name and tag line without a claim).

The above requirement is covered under Article 5.1 of the PhAMA Code of Practice, 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 materials (Exhibition Booths, brand reminders, brochures with product branding etc.) at Conferences in KL?

A: The restriction within the Code for display and distribution of branded promotional materials (Exhibition Booths, 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 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 ofsubstantiation. Comparative advertising should not be misleading.

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

A: Yes. A graph that has been adapted from a paper must state its source. A graph can be adapted provided it is clear and its true meaning not distorted.

10.3. Q: Can brand names of other companies' products be used as reference in CME events without prior consent from the proprietors?

A: No. Prior consent from the respective proprietors must be obtained.

10.4. Q: Can the image of a product without brand name be used as reference during CME events without prior consent from the proprietor?

A: Even if no product brand names of other companies is used, the product's image, whether capsules, tablets, medical devices or such, may be so unique that these items may be identifiable to a particular brand. Thus, prior consent must first be obtained, in compliance with the Trade Description Act 2011.

10.5. Q: Must 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 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 records. Member companies may however have an even stricter guideline which mandates additional course of actions.

11. Article Reprints (↑)

11.1 Q: Can companies reprint articles that mention certain product names? Thesereprints are not developed/lead by our company but by an external party, such as Community Service articles. Are clinical paper abstracts from publications allowed to be presented at the booth?

A: Reprints are acceptable as presentation if they are disease education articles only. Articles on promotional/branding of a prescription product is not allowed.

- Only full text is allowed i.e. publish as is.
- Abstracts are not allowed.
- Article reprints with product names 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 (↑)

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

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

13. Use of Quotations (↑)

13.1 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 sources identified. Quotationsshould 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. When used as stand-alone documents, reprints of scientific and medical articles that are not developed by pharmaceutical companies cannot be considered as promotional materials. However, if they are presented to a healthcare professional together with other company-originated documents, they are considered 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 ofartwork (including graphs, illustrations, photographs or tables) taken from articles orstudies 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 exact representations of the data shared in the reference literature to ensure there are no misunderstandings, 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 refers to 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: Does the term `venues associated with golf/spa' include venues that own and operate the golf course/spa only, or includes venues with a golf course/spa within its vicinity regardless of whether the golf course is owned/operated by the venue itself?

A: As a general rule, venues that directly own/operates golf courses/spa are not acceptable. 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 that offers the required facilities for the purpose of dissemination of scientific knowledge. The onus lies on the organisers to better plan their meetings and retain documentations of reasonable justification. 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 is held in luxurious and extravagant venues?

A: No. Refer to section 7.1.4.

16.3. Q: Is it acceptable for members to participate in conferences held at purpose-built conference facilities like the Sunway Convention Centre or Kuala Lumpur Convention Centre, even though they are located within entertainment surroundings as the venue itself was designated for the transfer of knowledge?

A: Yes, it is acceptable to utilize the facilities of venues that are clearly designated conference facilities.

16.4. Q: Is it acceptable for conference participants to utilize hotel accommodation within the vicinity of the designated conference facilities?

A: Yes. For pragmatic purposes, 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, however, have to exercise restraint and caution in their choice of accommodation to ensure it can withstand public scrutiny.

*In cases where member companies' overseas affiliates sponsor participants to Malaysia to participate in international scientific events held locally and choose their own accommodation for their sponsored participants, member companies are advised to share the PhAMA Code with their affiliate companies and provide a list of recommended hotels used for their own participants.

16.5. Q: As a local association, does PhAMA 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.

16.6. Q: Can member companies participate in Societies' or Medical Organization's scientific events which include the AGM component/activities?

A: It is acceptable as long as the scientific event is at least 75% of the total agenda and the activities during the AGM does not include unwarranted activities like fun fair, lucky draws, etc. Sponsorships provided by member companies should be strictly for scientific event and not for the AGM component/activities.

16.7 Q: Is there a guidance for limits of meeting packages? And when would a company be seen as exceeding the acceptable limit.

A: The cost of meeting packages should not be excessive. The Code has sufficient controls via guidelines on choices of venues for events and hospitality.

- The value of a meeting packages differs from one hotel to another.
- Each company should follow their own internal governance approval/processes in line with the PhAMA Code.
- Member companies were also advised to request the venue provider for itemised billing for clarity and transparency.

16.8 Q: Can member companies sponsor accommodations for healthcare providers attending companies' or third party scientific events held within the healthcare provider's state of practice?

A: Company to refer to their internal code for guidance and control, based on as-need basis (situation, timing/agenda, distance from event venue). Companies are advised to act in good faith and in accordance to the spirit of the PhAMA Code with regards to accommodations.

17. Entertainment (↑)

17.1 Q: How should companies interpret the requirement on entertainment?

A: When a company organizes a meeting and refreshments are provided, e.g. an evening meal (for a meeting stretching over one day), background music is permitted. However, it is inappropriate to utilize entertainment at a stand-alone meeting to attract 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 during a meal interlude.

17.2 Q: Is entertainment allowed in company sponsored or third-party events' booths?

Pure entertainment such as massage chairs, futsal or performances are not allowed. Activities related to education and disease awareness such as quizzes are allowed. However, gifts cannot be given out in such activities.

18. Sponsorship of HCP to CME Events (↑)

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?

A: The phrase ` Limited to maximum twice per year/company for each healthcare professional' refers only to international sponsorships held overseas, 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 to participate in the event. Any paid for services trip e.g. as chairperson, speaker, etc. or that for clinical research, are not included in the restriction. Note that sponsorship from either a local representative entity or the regional body is considered as sponsorship from the 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 service/ Honorarium (↑)

19.1 Q: Do members have to follow strictly to the honorarium guideline?

A: The honorarium is a token of appreciation to the healthcare providers for their time and effort taken for the knowledge transfer and inter-generational sharing of scientific experience that will develop the healthcare industry as a whole. While the Code serves as a general guide, members may apply the Code as deemed relevant.

19.2 Q: Section 7.4 of the PhAMA Code provision provides guidance for calculation of honorarium for local events but not for international events. Please provide the

justification for this omission and whether the same underlying principle applies to face to face international events as well as international virtual events?

A**:** In the international arena, the honorarium would take into consideration the fair market value and cost of living of the HCP's country. There is also a discrepancy of honorarium rates between Malaysia VS developed markets.

The omission of guidance for calculation of honorarium for international events allows companies the flexibility to ensure that the honorarium allocated to the local HCPs involved in international event is on par/comparable to that allocated tointernational speaker from other countries.

This underlying principle applies to both face to face and virtual scientific conferences.

Members are also advised to take into consideration their own company internal policy.

19.3 Q: Is there any guidance on honorarium for HCPs on long term engagements i.e. 3 or 6 months e.g. for projects like long-term disease awareness campaigns or collaborations with patient support groups?

A: No. Currently, such long-term projects does not fall under the scope of the PhAMA Code. The current guidance for honorarium applies to CMEs/Scientific events only.

19.4 Q: Does the same honorarium rate applies to nurses and members of the public?

A: The guidance applies to nurses as they are also categorised as HCPs. This guidance however does not apply to members of the public.

19.5 Q: A HCP is engaged as a speaker in a virtual conference. Due to risk of potential technical issues e.g. bandwidth and connectivity which may occur on the day of conference, the speaker is requested to pre-record the presentation prior to the actual conference. Is this considered 1 or 2 engagements? (The speaker has to share the same content twice and on different dates – recording will be used as back-up just in case).

A: If the HCP personally attends the virtual conference on both sessions, the engagement is considered as 2 engagements. This is regardless if he is personally presenting the slides or using the pre-recorded presentations during the actual virtual conference, as he may be required to address questions during the conference.

However, if he personally attends only one virtual session and only his pre-recorded presentation was played during the 2nd virtual session in his absence, it is considered as 1 engagement only.

Note: Pre-recording of the presentation is part of the preparation for the engagement.

19.6 Q: What is the definition of `per role' in the context of calculation of honorarium for HCPs? The term `per role' in the calculation of honorarium is quite ambiguous as a HCP may be requested to be a presenter as well as a Chairman at the same scientific event/conference.

A: The term 'per role' refers to the role that a HCP is expected to deliver during the specific event. The role may require different skill sets. To address the ambiguity, the term `per engagement' refers to  is amended to `per role'.

19.7 Q: Is there an hourly rate for speakers' fee, calculated based on the HCPs involvement on the actual conference day?

A: No. It would be difficult to put the value based on the HCPs presence at the conference. Calculation based on hourly rate may exceed the limit of RM4K/day. Furthermore, such calculation would not consider preparation time involved, nor allow the flexibility to consider the skill sets and expertise expected of the HCP during specific scientific forums.

19.8 Q: What is the guidance for the calculation of honorarium for HCPs engaged during scientific events? And how to calculate the total honorarium should a HCP be engaged to take on more than a role in a day?

A: In general, the calculation includes preparation work, experience or expertise required, and different categories of services before the actual engagement session.

The consideration towards the work involved includes whether it is a new topic, preparation of new slides or reusing an old slide, updates on present available slides or using the pharmaceutical companies' own slides. As such, the honorarium of HCPs at a scientific event should not be capped at minimum of RM2,000/role/day but instead 'up to max RM2,000/role/ engagement'.

Should the HCP be engaged as a Chairperson in addition to being a speaker at the same scientific event and the subject matter involved in both of the HCP's role does not differ greatly, the additional honorarium as a Chairperson may be calculated as a fraction of the fee of the HCPs capacity as a presenter. The calculation should not be on multiplication basis. As a guide, 80% of the total fee would be based on the speaker's content.

*Note: The honorarium as a Chairperson in an Advisory Board may be calculated at a much higher rate than that of a Chairperson at a normal scientific event, as the expectations, knowledge and skill sets during an Advisory Board session are much higher.

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

A: Kindly refer to the following:

i) Malaysian speaker in a local event:

If an honorarium is paid, the fair market value of the services provided is max RM2,000/engagement/day with up to maximum RM4,000/multiple engagement/day. A detailed signed contract on the services is required for auditing purposes and proof that it is not an inducement.

ii) A Malaysian speaker in an international event in Malaysia:

Companies should follow their internal company guidelines.

iii) A Malaysian speaker in an international event outside Malaysia: Companies should follow their internal company guidelines.

19.10 Q: What is the calculation of honorarium for healthcare providers taking on roles during a scientific event over several days?

A. Companies may decide on the additional days based on the guidance on per role engagement or

multiple roles engagement. Calculation of rates for additional days may not include preparation time, if the topic is the same.

20. Items of Medical Utility (↑)

20.1. Q: What items are envisaged as 'items of medical utility'?
A: Items of medical utility may be offered or provided, as long as they are of modest value, do not exceed RM500/item/HCP, 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 RM1,500 per institution or HCP. Items should not be offered on more than an occasional basis, even if each individual item is appropriate.

21.2. Can a thumb drive be given as medical utility?
A: This is acceptable as long as it is pre-loaded with education data or informational data with appropriate storage capacity.

21.3 Q: Can a company supply a book on a particular therapeutic area which includes Clinical Practice Guidelines to individual HCPs as item of medical utility?
A: Yes. Medical educational materials e.g. journals, textbooks and anatomy models can be provided to both institutions or HCPs, limited to the value of RM1,500 per year.

(The interpretation of institution should be maintained status quo at this point of time).

21.4 Q: Can information on a drug's specific Mode of Action, treatment of frequency and regimen, specific side effects be printed on a calendar and given to patients?
A: Calendars are not considered as items primarily for educational purposes. Furthermore, it has independent value.

21.3. Q: Can a company provide woven bags or as such with company logo and product brand names to conferences participants if the event was limited to HCPs only?
A: No. Refer to section 7.6 on promotional aids.

21. Sponsorships (↑)

21.1 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.

21.2 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: Companies 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.

22.4 Are PhAMA members allowed to sponsor HCPs for his/her Master Degree (via online) in the specialty related to the industry?
A: No.
- This is considered a gift as it confers a personal benefit to the HCP.

- A Masters Degree differs from a short scientific education programme/CME in that the latter relates to the objective of the company and is not for the personal benefit of HCPs.
- The short scientific programme/CME helps disseminate and enhance the knowledge among HCPs for the betterment of patient care.

22. Gifts (↑)

23.3. Q: Does PhAMA allow for infrequent Cultural Courtesy for local customs?
A: No.
Q: Is congratulatory flowers for any events allowed?
A: No.

23.4. Are food and beverage allowed to be provided to HCPs during product detailing activities?
A: This is not governed by the code. Please refer to your company's internal guidelines.

23.5. Q: Can food or beverage items with the company branding, taglines and logo of therapeutic area be given out to HCPs?
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: No, this is not allowed. Please refer to Section 7.6 on promotional aids.

23.7 Q: Can the company give out items for winners of quizzes, held during booth exhibitions?
A: No.

23.8 Q: Can companies send greeting card to HCPs with the logo of our Company and product brand?
A: Only the company logo is allowed in greeting cards.
- If there is a product name/logo, the material becomes a promotional material.
- If the logo is included, the contents of the material would have to adhere to the relevant provisions of the PhAMA Code.

23. Others (↑)

23.1 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.

23.2 Corporate membership fees-Is there any guidance from PhAMA as to whether societies should charge PhAMA members per event basis or a blanket annual fee for service fee rendered by the society on behalf of the company involved in any scientific event?

The services may involve but are not limited to:
- Application for CPD points by the society for specific events held in collaboration with the society
- Submission of post-event attendance list for point accreditation.
- Blasting of event e-flyers to all society members prior to event.
- Promotion of event at the society's website.

A: This does not fall within the scope of the PhAMA Code of Practice. However, every company has its own internal governance to formalise such arrangements. The services

rendered by the society must be itemised, documented and included in a signed document. This process must be undertaken for each event. An annual blanket fee is only acceptable if it is to cover for a series of the same event over a period of time.

23.3 Response to unsolicited queries pertaining to unapproved label use.

Can any suitably trained employees/Medical or Regulatory Department personnel respond to unsolicited queries pertaining to unapproved label use?

A: No. Queries on off label use should be addressed by the HCP's peers only i.e. medical doctors or pharmacists or those holding such functions. Being 'suitably trained' or the term 'department' does not reflect the criteria of the person responsible to address such queries.

Following are additional guidance:

- The professional training of medical and regulatory staff is irreplaceable.
- Decision on PhAMA Code has to be forward looking and agnostic to the general membership of PhAMA.
- It is important to uphold the standards of the industry and perception of stakeholders.
- Ensure that communications adhere to compliance.

24. Medical Devices (↑)

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

A: Yes. A medical device that accompanies a pharmaceutical product comes under the purview of the PhAMA Code. However, the definition of 'medical device' needs to be clear. For instance, a refrigerator (used for medicine storage) is not considered a medical device.

25. In-Vitro Studies (↑)

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

A: In-vitro, laboratory or animal data alone are insufficient to substantiate a clinical claim.

27. Gifts

Q2: Can gifts be presented to invitees during a company's corporate launch where invitees include HCPs, Government Officials and members of the public?

A2: If the event involves HCPs, the PhAMA Code applies.

Q3: Can promotional aids be provided to HCPs in conjunction with corporate launch events?

A3: No, as they will be considered as targeted at only specific HCPs who are invited.

Q4: Can promotional aids be provided randomly to the first 100 HCPS who register in conjunction with a corporate virtual launch event?

A4: No, as it will still be considered that the items were given to a targeted group of HCPs.

ADDENDUM: Guidance on Medical Samples to MOH Healthcare Facilities

The PhAMA Code of Practice for Prescription (Ethical) Products 22nd Edition ("Code") sets standards for industry practices for medical sampling. In response to the recent *Garis Panduan Pengendalian* Medicines Access Schemes ("MASc") *di Fasiliti Kementerian Kesihatan Malaysia* 1st Edition (2023), PhAMA is issuing this guidance on medical samples to MOH healthcare facilities.

In addition to the Code, the MASc now classifies medical samples as gift ("hadiah") to tighten the sampling processes. For details, please refer to MASc guidelines https://www.pharmacy.gov.my/v2/en/documents/garis-panduan-pengendalian-medicines-access-scheme-masc-fasiliti-kkm.html.

MOH has clarified that the definition of *hadiah* under the MASc guidelines is for MOH internal approval as MOH considers medical samples to be a form of gift. Member companies however are free to continue using industry applicable terms such as "medical samples", compassionate programme", "Patient Assisted Programme" and etc. In view of the same, member companies can continue to treat medical samples in accordance with Section 8 of the PhAMA Code of Practice and not as gifts (*hadiah)*.

Scope of the Guidance

The scope of this guidance is intended to cover all manner of medical samples offered by member companies to healthcare facilities under MOH. The Code sets out standards for the ethical sampling of medical products to healthcare professionals to ensure that member companies' interactions with healthcare professionals and medical institutions are appropriate and perceived as such. 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.

PhAMA in principle allows the sampling of medical products to healthcare professionals subject to the requirement of Section 8 of the Code as follows:

Section 8 - Samples:

8.1. Product samples 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 law.

8.2. Where products are restricted by law to be distributed by a representative upon prescription, the sample must be handed directly to the doctor or 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 securely to avoid 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, and should be used 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 monitor the samples whilst they are in the possession of medical representatives. If

the Member Company is aware of sample misuse, they have the right to discontinue sample distribution.

ADDENDUM: Virtual Interactions with Health Care Professional

The COVID-19 pandemic has led to new ways of working for biopharmaceutical companies, which have replaced (and/or added) in-office visits and face-to face congresses with virtual engagements to maintain dialogue and scientific exchange with the medical community while protecting the health and safety of patients, healthcare professionals and their own employees. Virtual interactions, meetings and congresses will continue and will become part of new normal.

The PhAMA Code of Pharmaceutical Marketing Practices 22.1 Edition set standards for industry business practices, which must be maintained in the virtual setting. In response to Company and Association questions, PhAMA are issuing this guidance on Virtual Interactions on different platform and including Medical Congresses. 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.

Scope of the Guidance

The scope of this guidelines is intended to cover all manner of interactions via digital platform, undertaken either via audio-visuals; and/or interactive virtual platform. This guidance additionally applies to International Congresses participation organized by medical associations/societies involving HCPs from multiple countries.

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.
While these requirements were originally drafted for in-person meetings, they apply similarly to virtual meetings.

Guidance

Promotional Material

PhAMA in principle allows the use of digital platform as a means of communication with HCPs, provided that the following requirements are complied with:

- Consent from the respective HCP is obtained prior to communicating;
- Virtual Interactions for business purposes should be communicated from a Company Profile and not associated to Personal Account
- The same requirement as applied to printed materials is complied with;
- The execution of the communication exercise via digital platform is not in conflict with other provisions of the PhAMA Code of conduct;
- Virtual mode of communication is approved by the respective company;
- The presentation (content, links, etc.) should be appropriate and apparent to the intended audience;

Meals during Virtual interactions

The PhAMA guidance allows provision of meals to HCPs participating in virtual meetings.

- Does not include HCPs who are attending the meetings from their home or clinics as they are already expected to be accessible to their daily meals.
- In a normal circumstances, hospitality may be extended to HCPs during meetings as the meeting would most probably be squeezed in during the HCPs meal time.
- Food vouchers will not be allowed in any initiatives as it is equivalent/ interchangeable with cash.
- Food vouchers is not expected to be utilized during the point of time of virtual meetings, but after and hence can have a cash value and thus not allowed.
- *Meals provided must be modest and reasonable by local standards; and as per internal guidance on value/limits of individual companies, therefore upholding the integrity and reputation of the industry.*

International Congress/Events Sponsorship/participation

As per PhAMA Code 7.2, Member companies may sponsor healthcare professionals to attend External International Events/meetings provided such sponsorship is in accordance with the following requirements. The same guidance will apply also Virtual International Congress/Events Sponsorships and participation:

- There are no limits to local sponsorships.
- Limited to maximum twice per year/company for each healthcare professional.
- Must not be conditional upon an obligation to prescribe, recommend, purchase, supply, administer or promote any pharmaceutical product.
- Sponsorship from either a local representative entity or from the regional body is considered as sponsorship from a same entity.
- Member Companies should ensure that a process is in place to confirm participants' status as HCPs/Non-HCPs (patient advocates, industry representatives, etc.).
- It is important for Companies to clearly state the label by which promotional materials were developed, to avoid any possible confusion.
- The promotional material must be accompanied by a statement indicating the countries in which the medicinal product is registered, and by an explanatory statement indicating that registration conditions differ internationally.
- Congress attendees should sign a digital consent indicating awareness/acknowledging Virtual Congress terms and conditions, such as specific permission to access different virtual areas (lectures, commercial expositions, social engagement sites, the basis of promotional material development, etc.).
- Even if this is the responsibility of the medical association/society, Companies need to be aware of the content of these kinds of Explanatory Statements/ Disclaimers.

- Companies should explore putting in place systems to appropriately address the situation where HCPs view materials from countries other than their own. Of particular concern is potential promotion directed to people not qualified to receive such content and promotion of unlicensed medicines and/or indications.

(Following are the provisions on relating the same topic in the current PhAMA Code of Practice 22.1 edition):

Section 13.5 of the PhAMA Code of Conduct

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 information.

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.

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.

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 the PhAMA Code of Practice (↑)

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
21.	Twentieth Edition	2017
22.	Twenty First Edition	2019
23.	Twenty Second Edition	2023