PhAMA CODE OF CONDUCT 21ST EDITION – 2019

FOR PRESCRIPTION (ETHICAL) PRODUCTS

Workshop Session

17 April 2019

HIGHTLIGHTS

Version 20th	Version 21st
1. Objective & Scope	1. Objective & Scope (Scope & Exclusions – update)
2. General Principles	2. General Principles
3. Pre-Approval Communications and Off-Label Use (Update)	3. Pre-Approval Communications and Off-Label Use
4. Standards of Promotional Information (Update)	4. Standards of Promotional Information
5. Printed Promotional Materials (Update)	5. Printed Promotional Materials (5.6 Distribution of promotional materials – update)
6. Electronic Materials including Audiovisuals (Update)	6. Electronic Materials including Audiovisuals
7. Interactions with HCPs (Update)	7. Interactions with HCPs (Limits, Gifts & other items, Prohibition of Cash and Personal Gifts, Promotional Aids, Items of Medical Utility, Informational or Educational Items, Cultural Courtesy - Update)
8. Samples (Update)	8. Samples
9. Clinical Research and Transparency	9. Clinical Research and Transparency

HIGHLIGHTS

Version 20th	Version 21th
10. Support for CMEs	10. Support for CMEs
11. Grants and Donations (New)	11. Grants and Donations
12. Interactions with Patient Organizations (12. 5 Disease Awareness - New)	12. Interactions with Patient Organizations (Public Disease Awareness Campaigns & Disease Awareness Campaigns to HCPs - New)
13. Relations with General Public and Lay Communication Media (13.5 Use of Social Media Communications - New)	13. Relations with General Public and Lay Communication Media
14. Company Procedures and Responsibilities	14. Company Procedures and Responsibilities
15. Infringement, Complaints and Enforcements	15. Infringement, Complaints and Enforcements
16. Valid Patent Rights	16. Valid Patent Rights
17. Operations of the Code (Appendix B - New)	17. Operations of the Code
18. Questions and Answers (Update)	18. Questions and Answers (Update)

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FOR PRESCRIPTION (ETHICAL) PRODUCTS

Training Slides

OBJECTIVES

- To highlight changes in the PhAMA code 21st edition.
- To share tools and resources available on the website – PhAMA Website (the code and PPT) and the IFPMA link – https://www.ifpma.org/resource-centre/ifpma-code-of-practice/

VISION & MISSION

NO CHANGE

OUR VISION

NO CHANGE

- Our vision is to be an organization working together with key stakeholders for better health and quality of life.

OUR MISSION

Our mission is to provide access to innovative medicines for better health and improved quality of life for all in Malaysia by:

NO CHANGE

- Promoting timely access to quality and innovative medicines
- Encouraging research and development of pharmaceutical products in Malaysia
- Forming strategic health partnership with key stakeholders for the advancement of public health
- Empowering consumers for safe and responsible self-medication
- Promoting industry values and contributing to the nation
- Upgrading the skills and knowledge of industry's human resources
- Ensuring the ethical promotion of medicines in compliance with local laws and a set of marketing practices

PhAMA CODE OF PHARMACEUTICAL MARKETING PRACTICES TWENTY FIRST EDITION

INTRODUCTION

CHANGE

INTRODUCTION

- The PhAMA Code of Pharmaceutical Marketing Practices was first drawn up and adopted by the membership in 1978. It has undergone constant review by the association and has been amended from time to time where necessary, to clarify it and bring it up-to-date.
- Notwithstanding any provision made under the Code, all marketing activities under the Code must conform to all existing and relevant government legislation governing the practice of the Pharmaceutical Industry.

NO CHANGE

INTRODUCTION

- 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.

NO CHANGE

INTRODUCTION

- The Administration of complaints and the procedure, which sets time frames for processing each complaint lodged, is outlined in the Code.
- The Code also includes explanatory notes to amplify the text and interpretation of the Code in some instances.

NO CHANGE

INTRODUCTION

- PhAMA, through its Ethics Committee shall be responsible for receiving and deliberating on all complaints, and in making decisions on each of them, and for communicating their decision to the complainant. The Ethics Committee shall publish the names of companies, which have been found to be in breach of the Code.
- Therefore, the major sanction against any company that transgresses the Code is the sanction of adverse publicity.

NO CHANGE

INTRODUCTION

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

NO CHANGE

INTRODUCTION

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

NO CHANGE

INTRODUCTION

- 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.

NO CHANGE

PROVISION OF THE CODE

1. **Objective & Scope**
2. (There is a separate Code that regulates OTC products)

NO CHANGE

OBJECTIVE

NO CHANGE

1.1 OBJECTIVE

- **Objective:** 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.

NO CHANGE

1.2 SCOPE
(FOR THE PURPOSES OF THE PHAMA CODE)

NO CHANGE

SCOPE: "PHARMACEUTICAL PRODUCT"

CLARIFICATION

- Means any pharmaceutical , 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 on the prescription of, or under the supervision of, a healthcare professional, and which is intended for use in the diagnosis, treatment or prevention of disease in humans, or to affect the structure or any function of the human body.

SCOPE: "PROMOTION"

NO CHANGE

- 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.

SCOPE: "HEALTHCARE PROFESSIONAL"

NO CHANGE

- 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.

SCOPE: "PATIENT ORGANIZATION"

NO CHANGE

- Means typically a not-for-profit institution that primarily represents the interests and needs of patients, their families and and/or caregivers.

SCOPE: "MEDICAL INSTITUTION"

NO CHANGE

- Means typically an organization that is comprised of healthcare professionals and/or that provides healthcare or conducts healthcare research.

SCOPE: "COMPANY"

NO CHANGE

- Means any company that is a member of PhAMA

SCOPE:

1.3 EXCLUSIONS

CHANGE

This Code does not seek to regulate the following activities:

- Promotion of self-medication products that are provided "over the counter" ~~with or without prescription~~
- Pricing or other trade terms for the supply of pharmaceutical products.
- The conduct of clinical trials.
- The provision of non-promotional information by member companies
- Public Disease Awareness Campaigns (Any mention is for purpose of providing clarity only)

2. GENERAL PRINCIPLES

NO CHANGE

2. GENERAL PRINCIPLES:
2.1 PRIORITY

NO CHANGE

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

2. GENERAL PRINCIPLES:
2.2 METHODS OF PROMOTION:

NO CHANGE

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

2. GENERAL PRINCIPLES:
2.3 BASIS OF INTERACTION

NO CHANGE

- 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. GENERAL PRINCIPLES:
2.4 INDEPENDENCE OF HEALTHCARE PROFESSIONALS

NO CHANGE

- No financial benefit or benefit-in-kind (including grants, sponsorships, gifts, scholarships, subsidies, support, consulting contracts or educational or practice related items) may be provided or offered to a healthcare professional in exchange for prescribing, recommending, purchasing, supplying or administering products or for a commitment to continue to do so.

- *N*othing 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. GENERAL PRINCIPLES:
2.5 APPROPRIATE USE

NO CHANGE

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

2. GENERAL PRINCIPLES:
2.6 TRANSPARENCY OF PROMOTION

NO CHANGE

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

2. GENERAL PRINCIPLES:
2.7 STANDARDS OF PROMOTION

NO CHANGE

- 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. GENERAL PRINCIPLES:
2.8 PRIVACY STATEMENT

NO CHANGE

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

CHANGES & ADDITION

3. PRE-APPROVAL AND OFF-LABEL COMMUNICATIONS

NO CHANGE

3. PRE-APPROVAL AND OFF-LABEL COMMUNICATIONS

- No pharmaceutical product shall be promoted in Malaysia until the requisite regulatory approval for marketing for such use has been given.
- This provision is not intended to prevent the right of scientific community and the public to be fully informed concerning scientific and medical progress.

NO CHANGE

3. PRE-APPROVAL AND OFF-LABEL COMMUNICATIONS

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

NO CHANGE

3. PRE-APPROVAL AND OFF-LABEL COMMUNICATIONS

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

NO CHANGE

4. STANDARDS OF PROMOTIONAL INFORMATION

NO CHANGE

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.

NO CHANGE

4. STANDARDS OF PROMOTIONAL INFORMATION:
4.2 SUBSTANTIATION

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

NO CHANGE

4. STANDARDS OF PROMOTIONAL INFORMATION:
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.
- (continued…)

NO CHANGE

4. STANDARDS OF PROMOTIONAL INFORMATION:
4.3 CLAIMS & COMPARISONS

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

NO CHANGE

4. STANDARDS OF PROMOTIONAL INFORMATION:
4.3 CLAIMS & COMPARISONS

- (…continued)
- The word "new" should not be used to describe any product or presentation which has been generally available, or any therapeutic indication for which the product / indication has been registered in Malaysia for more than 18 months.
- **Brand names of products of other companies must not be used unless prior consent of the proprietors has been obtained.**

NO CHANGE

4. STANDARDS OF PROMOTIONAL INFORMATION:
4.4 DISPARAGING REFERENCES

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

NO CHANGE

5. PRINTED PROMOTIONAL MATERIALS

NO CHANGE

5. PRINTED PROMOTIONAL MATERIALS

5.1 ALL PRINTED PROMOTIONAL MATERIAL, INCLUDING ADVERTISEMENTS:

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

- the brand name of the product;
- the active ingredients, using approved names where they exist;
- the name and address of the pharmaceutical company or its agent responsible for marketing the product;
- date of production of the advertisement; and
- "abbreviated prescribing information" which should include an approved indication together with the dosage and method of use; and a succinct statement of the contraindications, precautions and side effects **A minimum font size of 6 points is to be used for printed materials*

NO CHANGE

5. PRINTED PROMOTIONAL MATERIALS:
5.2 ALL PRINTED PROMOTIONAL MATERIAL

(other than those covered in Article 5.3)

Should also fulfill the following requirements):

- Promotional material such as mailings and journal advertisements and loose inserts must not be designed to disguise its real nature.
- Advertisements in journals should not be designed so as to resemble editorial material.

NO CHANGE

5. PRINTED PROMOTIONAL MATERIALS:
5.2 ALL PRINTED PROMOTIONAL MATERIAL

- Promotional material should conform, both in text and illustration, to canons of good taste and should recognise the professional standing of the recipient.
- All printed promotional material, including advertisements should include the name of the product (normally the brand name) generic name of the product and the date of production of the advertisement.
- Doctors' names or photographs must not be used in a prominent manner in promotional material or in any way that is contrary to the ethical code of the medical profession.

NO CHANGE

5. PRINTED PROMOTIONAL MATERIALS:
5.2 ALL PRINTED PROMOTIONAL MATERIAL

- Promotional material should not imitate the devices, copy, slogans or general layout adopted by other companies in a way that is likely to mislead or confuse.
- Material and articles from the lay press should not be used as promotional material.
- Disclaimer statement "For Healthcare Professionals only" to be added to printed materials for the HCP targeted audience

NO CHANGE

5.3 REMINDER ADVERTISEMENTS

NO CHANGE

5.3 REMINDER ADVERTISEMENTS

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

NO CHANGE

5.4 ARTWORK, GRAPHICS, ILLUSTRATIONS, ETC IN PRINT AND OTHER MEDIA

NO CHANGE

5.4 ARTWORK, GRAPHICS, ILLUSTRATIONS, ETC IN PRINT AND OTHER MEDIA

- Illustrations must not mislead as to the nature of the claims or comparisons being made, nor as to the purpose for which the product is used.
- Artwork and graphics must conform to the letter and the spirit of the Code. Graphs and tables should be presented in such a way so as to give a clear, fair, balanced view of the matters with which they deal, and should only be included if they are relevant to the claims or comparisons being made.

NO CHANGE

5.4 ARTWORK, GRAPHICS, ILLUSTRATIONS, ETC IN PRINT AND OTHER MEDIA

- Graph and tables must not be used in any way which might mislead, for example by the incompleteness or by the use of suppressed zeros or unusual scales.
- If a graph has been adapted from a paper, it must be stated so. A graph can be adapted; provided it is clear and its true meaning is not distorted.

NO CHANGE

5.5 REPRINTS, ABSTRACTS AND QUOTATIONS IN PRINT OR OTHER MEDIA

NO CHANGE

5.5 REPRINTS, ABSTRACTS AND QUOTATIONS IN PRINT OR OTHER MEDIA

- Material from medical literature or from personal communications received from doctors must accurately reflect the meaning of the author and the significance of the study (which should not be distorted by the addition of printed highlighting or underlining to give prominence to selected portions of the material).
- Care must be taken to avoid ascribing claims or views relating to the medical products to authors when such claims or views no longer represent or may not represent the current view of the authors concerned.

NO CHANGE

5.6 DISTRIBUTION OF PROMOTIONAL MATERIAL

NO CHANGE

5.6 DISTRIBUTION OF PROMOTIONAL MATERIAL

- Promotional material should only be sent or distributed to those categories of persons whose need for or interest in the particular information can reasonably be assumed, but must not exceed the categories sanctioned by law.
- Any information with regards to the use of pharmaceutical products in clinics or industrial concerns must be addressed to Health Care Professionals (HCP).

NO CHANGE

5.6 DISTRIBUTION OF PROMOTIONAL MATERIAL

- No promotional material shall be issued unless the final text and layout have been certified by a senior official preferable from medical/regulatory department of the company, preferably a doctor or a pharmacist.
- ~~The certificate shall certify that the signatories have examined the material and that in their belief it is in accordance with all legal and ethical requirements of the Code.~~
- ~~Companies shall preserve all certificates, together with the material in the form certified, for not less than 3 years and produce them upon request from the Ethics Committee.~~

REMOVED

6. ELECTRONIC MATERIALS, INCLUDING AUDIOVISUALS

NO CHANGE

6. ELECTRONIC MATERIALS, INCLUDING AUDIOVISUALS

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

Specifically, in the case of pharmaceutical product related websites:

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

NO CHANGE

7. INTERACTIONS WITH HEALTHCARE PROFESSIONALS

NO CHANGE

7. INTERACTIONS WITH HEALTHCARE PROFESSIONALS

7.1 Events and Meetings

NO CHANGE

7.1 EVENTS AND MEETINGS:
7.1.1 SCIENTIFIC AND EDUCATIONAL OBJECTIVES

- The purpose and focus of all symposia, congresses and other promotional, scientific or professional meetings (an "Event") for healthcare professionals organized or sponsored by a company should be to provide scientific or educational information and/or inform healthcare professionals about products.
- Any financial support of medical societies, hospitals and clinics' social event e.g. annual general meeting, annual dinner, family day, sports day, etc. in the form of donation and/or gifts are not allowed.

NO CHANGE

7.1 EVENTS AND MEETINGS:
7.1.2 EVENTS INVOLVING FOREIGN TRAVEL

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

NO CHANGE

7.1.3 DISSEMINATION OF INFORMATION OF UNAPPROVED PRODUCT OR INDICATION

Local Meetings inclusive of CME's

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

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

NO CHANGE

7.1 EVENTS AND MEETINGS

7.1.3 DISSEMINATION OF INFORMATION OF UNAPPROVED PRODUCT OR INDICATION

- **International Meetings**

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

•The meeting should be a truly international, scientific Event with a significant proportion of the speakers and attendees from countries other than the country where the Event takes place; *(7.2 of PhAMA)*

NO CHANGE

7.1.3DISSEMINATION OF INFORMATION OF UNAPPROVED PRODUCT OR INDICATION

- **International Meetings**

•Information (excluding promotional aids) for a pharmaceutical product not registered in Malaysia should be accompanied by a suitable statement indicating that the product/indications/dosage form is not registered and make clear that the product/indication/dosage is still unapproved in Malaysia

•Information which refers to the prescribing information (indications, warnings etc.,) authorized in a country or countries other than Malaysia but where the product is also registered, should be accompanied by an explanatory statement indicating that registration conditions differ internationally.

NO CHANGE

7.1 EVENTS AND MEETINGS
7.1.4 APPROPRIATE VENUE

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

Companies should not organize Events nor provide financial support including sponsoring HCPs to any event at renowned or venues not appropriate for purpose of scientific education associated with leisure, golf, spa, island resorts (not accessible by land transport) and gaming activities. *(continued…)*

NO CHANGE

7.1 EVENTS AND MEETINGS
7.1.4 APPROPRIATE VENUE

(…continued)

The venue should be:

- appropriate for the meeting (e.g. adequate facilities for the number of attendees/good internet access)

- appropriate and conducive to the scientific or educational objective and purpose of the event or meeting

- located so as to minimise travel for attendees

- having adequate security

- able to successfully withstand public and professional scrutiny.

NO CHANGE

QUESTIONS & ANSWERS

Q&A

Venues Associated with Golf & Spa

IS THE TERM `VENUES ASSOCIATED WITH GOLF/SPA' INCLUDES VENUES WHICH OWNS AND OPERATES THE GOLF COURSE/SPA ONLY OR AS WELL AS VENUES WHICH HAVE A GOLF COURSE/SPA WITHIN ITS VICINITY REGARDLESS OF WHETHER THE GOLF COURSE IS OWNED/OPERATED BY THE VENUE ITSELF?

- As a rule, venues which directly own/operates golf courses/spa are not acceptable. ~~`Venues associated with golf/spa' may also refer to venues which do not necessarily owns or manages the golf course/spa itself. However, v~~Venues which are near/within the vicinity of a golf course/spa may be accepted if there are no other alternative venues within the vicinity which offers the required facilities for the purpose of dissemination of scientific knowledge.
- It is the onus of the members to better plan their meetings and retain documentations of reasonable justification. Such due diligence should be made available upon request. Refer to section 7.1.4.

REPHRASED

Q&A

Extravagant venues

CAN A PHAMA MEMBER COMPANY PARTICIPATE IN A MEDICAL SOCIETY'S SCIENTIFIC EVENT IF IT WERE TO BE HELD IN LUXURIOUS AND EXTRAVAGANT VENUES?

No. Refer to section 7.1.4.

- ~~Q: Can a member utilize a venue which is considered 'inappropriate venue' as it may be the only venue which offers reasonably meeting facilities within the vicinity?~~

- ~~A: As a rule, no. It requires good planning from the members' end to ensure that only venues which are considered appropriate are utilized for their function. It is the onus of the members to better plan their meetings and retain documentations of reasonable justification. Such due diligence should be made available upon request.~~

CHANGE

7.1 EVENTS AND MEETINGS:
7.1.5 LIMITS

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

-exclusively to participants of the Event~~; and~~

-if they are moderate and reasonable as judged by local standards.

-~~l~~light refreshments of no more than RM15/item can be provided at scientific booths and has to be secondary in nature. ~~Coffee barista is not considered as secondary in nature.~~

CHANGE

QUESTIONS & ANSWERS

Q&A

Limits – Branding on F&B items

CAN FOOD OR BEVERAGE ITEMS WITH THE COMPANY BRANDING, TAG LINES AND LOGO OF THERAPEUTIC AREA BE GIVEN OUT TO HCPS?

- A: No.

NEW

7.1 EVENTS AND MEETINGS:
7.1.6 ENTERTAINMENT

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

NO CHANGE

7.1 EVENTS AND MEETINGS:
7.1.7 OTHER ACTIVITIES

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

NO CHANGE

QUESTIONS & ANSWERS

Q&A

Entertainment in scientific booths

IS ENTERTAINMENT ALLOWED IN COMPANY SPONSORED OR THIRD-PARTY EVENTS' BOOTHS?

- Pure entertainment such as massage chairs, futsal or performances are not allowed. Refer to section 7.1.6.
- Activities related to education and disease awareness such as quiz are allowed. However, gifts cannot be given out in such activities. Refer to section 7.6.

NEW ADDITION

7. INTERACTIONS WITH HEALTHCARE PROFESSIONALS

7.2 Sponsorships

NO CHANGE

7. INTERACTIONS WITH HEALTHCARE PROFESSIONALS:
7.2 SPONSORSHIPS

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

- The Event complies with the requirements in this Code as described in 7.1;
- Sponsorship to healthcare professionals is limited to the payment of travel, meals, accommodation and registration fees;
- Only cover basic economy travel (if travelling time is less than 6 hours)
- Limited to maximum twice per year/company for each healthcare professional.

NO CHANGE

7. INTERACTIONS WITH HEALTHCARE PROFESSIONALS:
7.2 SPONSORSHIPS

- The cost of the most direct route will be funded.
- No payments are made to compensate healthcare professionals for time spent in attending the Event; and
- Any sponsorship provided to individual healthcare professionals must not be conditional upon an obligation to prescribe, recommend, purchase, supply, administer or promote any pharmaceutical product.

NO CHANGE

QUESTIONS & ANSWERS

Q&A

Societies' & Medical Organizations'
Scientific Event with AGM content

ARE MEMBER COMPANIES' PARTICIPATION AT SOCIETIES' OR MEDICAL ORGANIZATION'S SCIENTIFIC EVENTS WHICH INCLUDES THE AGM COMPONENT/ACTIVITIES ALLOWED?

- ~~It would be inevitable for any society or organization to hold their AGM back to back or as part of agenda for CME events to cut costs as well as due to the logistic and time convenience it accords.~~
- As long as the scientific event is at least 75% of the total agenda and that the activities during the AGM do not include unwarranted activities like fun fair, lucky draws, etc. It would be acceptable. Refer to sections within 7.1.7.
- Sponsorships provided by member companies should be strictly for scientific event and not for the AGM component/activities. Refer to sections 7.1.1.

CHANGE

7. INTERACTIONS WITH HEALTHCARE PROFESSIONALS

7.3 Guest

NO CHANGE

7. INTERACTIONS WITH HEALTHCARE PROFESSIONALS

7.3 GUEST

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

NO CHANGE

7. INTERACTIONS WITH HEALTHCARE PROFESSIONALS

7.4 Fees for Services

NO CHANGE

7. INTERACTIONS WITH HEALTHCARE PROFESSIONALS:
7.4 FEES FOR SERVICES

- Health care professionals may be engaged as consultants and advisors for services such as speaking at and/or chairing meetings and events, involvement in training services and participation at advisory board meetings where such participation involves remuneration. The arrangements which cover these genuine consultancies or other services must, to the extent relevant to the particular arrangement, fulfill all the following criteria:

- a written contract or agreement must be agreed in advance of the commencement of the services which specifies the nature of the services to be provided and the basis for payment of those services; (continue…)

NO CHANGE

7. INTERACTIONS WITH HEALTHCARE PROFESSIONALS:
7.4 FEES FOR SERVICES

- *(…continue…)*

- a legitimate need for the services must be clearly identified and documented in advance;

- the criteria for selecting consultants must be directly related to the identified need and the consultants must have the expertise necessary to provide the service;

- the number of consultants retained must not be greater than the number reasonably necessary to achieve the identified need;

- the hiring of the consultant to provide the relevant service must not be an inducement to prescribe, recommend, purchase, supply, and/or administer any medicine; and *(continue…)*

NO CHANGE

7. INTERACTIONS WITH HEALTHCARE PROFESSIONALS:
7.4 FEES FOR SERVICES

- *(…continued)*
- • the fair market value of the services provided is RM1,500.00/engagement/day with up to maximum RM3,000.00/multiple engagement/day.
- •If it concerns local speakers at international even ts held locally or outside Malaysia, members are advised to refer to their own company's internal code. The same proposal on a signed contract remains.
- •If it concerns international speakers, then members are advised to check with the speaker's home country code and apply accordingly. The same proposal on a signed contract remains.

NO CHANGE

7. INTERACTIONS WITH HEALTHCARE PROFESSIONALS

7.5 Marketing Research

NO CHANGE

7.5 MARKETING RESEARCH:
7.5.1 METHODS EMPLOYED

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

NO CHANGE

7.5 MARKETING RESEARCH:
7.5.2 QUESTIONS

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

NO CHANGE

7.5 MARKETING RESEARCH:
7.5.3 INCENTIVES

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

NO CHANGE

7.5 MARKETING RESEARCH:
7.5.4 TRANSPARENCY

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

NO CHANGE

7.5 MARKETING RESEARCH:
7.5.4 TRANSPARENCY

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

NO CHANGE

7. INTERACTIONS WITH HEALTHCARE PROFESSIONALS:
7.5.5 OBJECTIVE

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

NO CHANGE

7. INTERACTIONS WITH HEALTHCARE PROFESSIONALS:
7.5.6 IDENTITY OF INFORMANT

- The identity of an informant must be treated as confidential, unless he has specifically agreed otherwise.
- (In the absence of this agreement, it follows that the information provided as distinct from the overall results of the research must not be used as the basis upon which a subsequent approach is made to that informant for the purpose of sales promotion.)

NO CHANGE

7. INTERACTIONS WITH HEALTHCARE PROFESSIONALS

7.6 Gifts and other Items

NO CHANGE

7. INTERACTIONS WITH HEALTHCARE PROFESSIONALS:
7.6 GIFTS AND OTHER ITEMS

- Items in this section where permissible, must never constitute an inducement to prescribe, recommend, purchase, supply, sell or administer a pharmaceutical product.
- Participation or any support in the form of financial donation and/or gifts are not allowed for medical societies, hospitals and clinics' social event e.g. annual general meeting, annual dinner, family day, sports day, etc.

CHANGE - ADD

7. INTERACTIONS WITH HEALTHCARE PROFESSIONALS:
7.6 GIFTS AND OTHER ITEMS

- ~~Inappropriate financial or material benefits, including inappropriate hospitality, should not be offered to healthcare professionals to influence them in the prescription of pharmaceutical products.~~
- ~~Any financial support of medical societies, hospitals and clinics' social event e.g. annual general meeting, annual dinner, family day, sports day, etc. in the form of donation and/or gifts are not allowed~~.

REMOVED

QUESTIONS & ANSWERS

Q&A

Gifts & Other Items

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?

- This is not allowed.
- Reason for change – to reflect that corporate advertisement or support in kind should only be for scientific event. Refer to section 7.6.

NO CHANGE

7. INTERACTIONS WITH HEALTHCARE PROFESSIONALS:

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 is also prohibited For these purposes, personal services are any type of service unrelated to the HCP's profession and that confer a personal benefit to the HCP.

CHANGE

7. INTERACTIONS WITH HEALTHCARE PROFESSIONALS:

7.6.1 PROHIBITION OF CASH AND PERSONAL GIFTS

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

REMOVED

QUESTIONS & ANSWERS

Q&A

Gifts & Other Items – Cultural Courtesy

DOES PhAMA ALLOW FOR INFREQUENT CULTURAL COURTESY FOR LOCAL CUSTOMS?

- No. Refer to section 7.6.1.

- ~~Yes, it is allowed and may be given not more than twice per year to a healthcare professional in acknowledgement of significant festive occasion~~.

CHANGE

Q&A

Gifts – F&B Item with Branding

CAN FOOD OR BEVERAGE ITEMS WITH THE COMPANY BRANDING, TAG LINES AND LOGO OF THERAPEUTIC AREA BE GIVEN OUT TO HCPS?

- A: No.

NEW

7. INTERACTIONS WITH HEALTHCARE PROFESSIONALS:
7.6.2 PROMOTIONAL AIDS

- ~~**7.6.2 Promotional Aids**~~
- ~~Promotional aids whether related to a particular product or of general utility, may be distributed provided the promotional aid is of small value (not more than RM100.00) and directly relevant to the practice of medicine or pharmacy or of benefit to patient care.~~

REMOVED

7. INTERACTIONS WITH HEALTHCARE PROFESSIONALS:
7.6.2 PROMOTIONAL AIDS

- **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 in relation to the promotion of prescription-only medicines is prohibited. Examples of banned promotional aids include sticky notes, mouse pads, calendars, etc.

CHANGE

7. INTERACTIONS WITH HEALTHCARE PROFESSIONALS:
7.6.2 PROMOTIONAL AIDS

Pens and notepads can be provided to HCPs in the context of company organized events or third-party scientific events for the purpose of taking notes during the meeting. They must not bear the name of any medicine, campaign names, tag lines and logos of therapeutic area but may bear the name of the company providing them. In addition, they must be of minimal value i.e. no more than RM 15 nett per item and only the necessary quantity is distributed.

CHANGE

7. INTERACTIONS WITH HEALTHCARE PROFESSIONALS:
7.6.2 PROMOTIONAL AIDS

(Pens and notepads or any other types of items considered as promotional aids or gifts are not allowed to be distributed during booth exhibitions).

Thumb drive is allowed if the purpose is used 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.

CHANGE

7. INTERACTIONS WITH HEALTHCARE PROFESSIONALS:
7.6.2 PROMOTIONAL AIDS

- ~~**7.6.2 Promotional Aids**~~
- ~~Promotional aids whether related to a particular product or of general utility, may be distributed provided the promotional aid is of small value (not more than RM100.00) and directly relevant to the practice of medicine or pharmacy or of benefit to patient care.~~

REMOVED

7. INTERACTIONS WITH HEALTHCARE PROFESSIONALS:
7.6.2 PROMOTIONAL AIDS

- ~~**7.6.2.1** Reminders are designed just to remind a prescriber of a product's existence and must not contain a promotional claim which includes the mention of any indication. A reminder must contain:~~
- ~~(a) Brand name of the product;~~
- ~~(b) Approved name(s) of the active ingredients(s);~~
- ~~(c) Name of the supplier.~~
- ~~**7.6.2.2** If a reminder contains tag lines or slogans, the name of supplier as well as a statement that further information is available on requests, must be included.~~

REMOVED

QUESTIONS & ANSWERS

Q&A

Items of medical utility – Woven bag with company or product branding

MAY A COMPANY PROVIDE WOVEN BAGS OR AS SUCH WITH COMPANY'S LOGO AND PRODUCT BRAND NAMES TO CONFERENCES PARTICIPANTS IF THE EVENT WAS LIMITED TO HCPS ONLY?

-
- No. Refer to section 7.6.

NEW

Q&A

Promotional aids – Accompanying item

CAN FILE OR FOLDER BE INCLUDED TOGETHER WITH THE PENS AND NOTE PADS/THUMB DRIVES?

Pens and notepads and thumb drives are the only exception to the rule of no promotional aids. Refer to section 7.6.2.

NEW

Q&A

Promotional aids - Branding

CAN WE PRINT THE NAME OF SCIENTIFIC EVENT ON THE NOTE PADS?

- No. Only company branding is allowed on promotional aids. Refer to section 7.6.2.

NEW

Q&A

Promotional Aids - For HCPs

CAN PROMOTIONAL AIDS BE DISTRIBUTED TO HCPS DURING VISITS TO CLINICS?

- No. Refer to section 7.6.2.

NEW

Q&A

Promotional aids – Distributed at Exhibition Booths

ISN'T BOOTH EXHIBITION CONSIDERED PART OF 3RD PARTY SCIENTIFIC EVENT? CAN PROMOTIONAL AIDS BE DISTRIBUTED AT THE BOOTHS?

- No. Pens and note pads are allowed for purpose of taking notes during scientific events only.

NEW

Q&A

Promotional aids during short luncheon talks

CAN PENS & NOTE PADS BE DISTRIBUTED DURING SHORT LUNCHEON SCIENTIFIC TALKS?

- A: Yes, they are allowed.

NEW

7. INTERACTIONS WITH HEALTHCARE PROFESSIONALS:

7.6.3 INFORMATIONAL OR EDUCATIONAL MATERIALS AND ITEMS OF MEDICAL UTILITY

- 7.6.3.1 Educational Materials Items that enhance Patient Care

- Informational or educational items provided to HCPs for their education or for the education of patients on disease and its treatments may be offered by member companies provided that the items are primarily for educational purposes and do not have independent value.

CHANGE - ADD

7. INTERACTIONS WITH HEALTHCARE PROFESSIONALS:

7.6.3 INFORMATIONAL OR EDUCATIONAL MATERIALS AND ITEMS OF MEDICAL UTILITY

- Informational or educational items provided for HCPS

- Informational or educational items provided to HCPs for their education may be offered by member companies provided that the items are primarily for educational purposes and do not have independent value.
- The items provided are of direct educational value and have no direct promotional value and should not be offered on more than an occasional basis.
- (To continue)

CHANGE

7. INTERACTIONS WITH HEALTHCARE PROFESSIONALS:

7.6.3 INFORMATIONAL OR EDUCATIONAL MATERIALS AND ITEMS OF MEDICAL UTILITY

(…continued)

- Informational or educational items provided for HCPS
- The value of medical educational material to institutions or HCPs e.g. journals, textbook, anatomy models and subscription must not exceed RM1,500.00/year per institutions or HCPs.
- It is acceptable to print/put the company's branding on any educational materials. Product branding, product campaign names, tag lines and logos of therapeutic areas are not allowed.

CHANGE

7. INTERACTIONS WITH HEALTHCARE PROFESSIONALS:

7.6.3 INFORMATIONAL OR EDUCATIONAL MATERIALS AND ITEMS OF MEDICAL UTILITY

- Informational or educational items provided for education of patients on disease and its treatments

- The items offered for the education of patients or disease and its treatments may be offered by member companies provided that the items are primarily for educational purposes and do not have independent value.
- Informational and educational items provided for the education of patients on disease and its treatments can include the company name, but must not be product branded, unless the product's name is essential for the correct use of the item by the patient.

CHANGE - ADD

7. INTERACTIONS WITH HEALTHCARE PROFESSIONALS:

7.6.3 INFORMATIONAL OR EDUCATIONAL MATERIALS AND ITEMS OF MEDICAL UTILITY

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

- Items of medical utility may be offered or provided by member companies if such items are of modest value, do not exceed RM500.00/item/HCP, do not offset routine business practices and are beneficial to enhancing the provision of medical services and patient care.
- Items such as stethoscopes, surgical gloves, blood pressure monitors and needles are examples of routine business expenses , and they are expected to be supplied by the HCPs themselves or their employers. (To be continued)

CHANGE

7. INTERACTIONS WITH HEALTHCARE PROFESSIONALS:

7.6.3 INFORMATIONAL OR EDUCATIONAL MATERIALS AND ITEMS OF MEDICAL UTILITY

- (Continued)
- They should not be offered on more than occasional basis, even if each individual items is appropriate.
- It is acceptable to print/put the company's branding on any educational materials. Product branding, product campaign names, tag lines and logos of therapeutic areas are not allowed.

CHANGE

~~7. INTERACTIONS WITH HEALTHCARE PROFESSIONALS: 7.6.4CULTURAL COURTESY~~

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

REMOVED

QUESTIONS & ANSWERS

Q&A

Items of medical utility

WHAT KINDS OF ITEMS ARE ENVISAGED AS BEING ITEMS OF MEDICAL UTILITY?

- Items of medical utility may be offered or provided, provided that such items are of modest value, do not exceed RM500.00/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 RM1,500.00 per institution or HCP. Items should not be offered on more than an occasional basis, even if each individual item is appropriate. Kindly refer to sections 7.6.3.1 and 7.6.3.2

CHANGE

Q&A

Items of medical utility

CAN A THUMB DRIVE BE GIVEN AS MEDICAL UTILITY?

- This is acceptable as long as it is pre-loaded with education data or informational data with appropriate storage capacity.

NEW

Q&A

Items of medical utility

MAY A COMPANY SUPPLY A BOOK ON A PARTICULAR THERAPEUTIC AREA WHICH INCLUDES CLINICAL PRACTICE GUIDELINES TO INDIVIDUAL HCPS AS ITEM OF MEDICAL UTILITY?

- Yes, Medical educational material e.g. journals, textbooks & anatomy models can be provided to both institutions or HCPs and the limit is extended to RM1,500.00 per year. Refer to section 7.6.3.

- ~~Medical educational material e.g. journals, textbooks & anatomy models can be provided to institutions only and the limit is extended to RM1,000.00 per year. Items of Medical Utility which has direct relevance to the practice of a clinic can be provided as long as it does not exceed RM500.00.~~

- ~~(Whilst there were opinions that the medical educational materials of up to RM1,0500.00 should be allowed to be provided to clinics as well instead of to institutions only; as there are clinics which have branches or a few doctors which has grouped up to open up a clinic ittee holds the opinion that the interpretation of institution should be maintained status quo at this point of time).~~

CHANGE

Q&A

Items of medical utility – Rubber Stamps

CAN THE INDUSTRY PROVIDE HEALTHCARE PROFESSIONALS WITH RUBBER STAMPS OF THE GENERIC NAME OF A PRODUCT WITH ITS ACCOMPANYING PRESCRIPTION REQUIREMENT?

No. This is not allowed. Please refer to Section 7.6.

NEW

Q&A

Items of medical utility – Usage of calendars

CAN INFORMATION ON DRUG'S SPECIFIC MODE OF ACTION, TREATMENT OF FREQUENCY & REGIMEN, SPECIFIC SIDE EFFECTS BE PRINTED ON A CALENDAR AND GIVEN TO THE PATIENTS?

- Calendar is not an item considered as primarily for educational purposes. Furthermore, it has independent value. Refer to section 7.6.3.

NEW

Q&A

Items of Medical Utility

CAN WE PRINT THE NAME OF THE SCIENTIFIC EVENT ON THE NOTE PADS?

- No. Only company branding is allowed for promotional items. Refer to section 7.6.3.

NEW

8. SAMPLES

NO CHANGE

8. SAMPLES

- **8.1** Samples of products given out should be no larger than the smallest commercial pack of each strength and clearly labeled as "Samples – not for sale" or similar wording allowed by the law.
- **8.2** Where samples of products restricted by law to supply on prescription are distributed by a representative, the sample must be handed direct to the doctor or given to a person authorised to receive the sample on his behalf.
- **8.3** Samples must be delivered conforming to the Postal and Poisons Regulations governing it, and must be packed so as to be reasonably secure against the package being opened by children. (Refer to the Ethics Committee & RAC) *(continued…)*

NO CHANGE

8. SAMPLES

(…continued)

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

NO CHANGE

8. SAMPLES
8.5 CONTROL AND ACCOUNTABILITY

- Companies should have adequate systems of control and accountability for samples provided to healthcare professionals including how to look after such samples whilst they are in the possession of medical representatives.
- In any case where the Member Company is in knowledge of misused of samples *(by HCP)*, the member company has the right to discontinue sample distribution.

NO CHANGE

9. CLINICAL RESEARCH & TRANSPARENCY

NO CHANGE

9. CLINICAL RESEARCH AND TRANSPARENCY

9.1 TRANSPARENCY

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

NO CHANGE

9. CLINICAL RESEARCH AND TRANSPARENCY

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.

NO CHANGE

10. SUPPORT FOR CONTINUING MEDICAL EDUCATION

NO CHANGE

10. SUPPORT FOR CONTINUING MEDICAL EDUCATION

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

NO CHANGE

10. SUPPORT FOR CONTINUING MEDICAL EDUCATION

- When companies provide content to CME activities and programs, such material must be fair, balanced and objective, and designed to allow the expression of diverse theories and recognized opinions. Content must consist of medical, scientific or other information that can contribute to enhancing patient care.
- On a professional basis, a doctor or pharmacist under the employment of a member company is allowed to attend Scientific meetings under the umbrella of a professional Society or Organisation of which he is a member (e.g., MMA, MPS) even though it may be organized by a competitor company.

NO CHANGE

11. GRANTS & DONATIONS

NO CHANGE

11. GRANTS & DONATIONS

- Donations are for charitable purposes and for charitable organisations.
- Grants are provided to support educational programmes (including but not limited to requests to fund CME programmes, educational programmes, fellowships, advocacy organisations, societies, medical conferences and congresses) if they are:
  - Unsolicited
  - From an institution or organisation, not from an individual
  - Unrelated to the prescribing, purchasing, registration of any products
  - Substantiated by written documentation of details of programme
  - Able to withstand public scrutiny *(continued…)*

NO CHANGE

11. GRANTS & DONATIONS

- *(…continued)*
- As a general rule, grants and donations should not be provided for the purpose of supporting a recipient's ordinary business expenses, e.g. for infrastructure or overhead (such as the purchase, construction, expansion, or modification of facilities or equipment and paying of salaries).
- Institutions or organisations must ensure that the recipients use the donations and grants in accordance with the intended purposes independent from the companies providing the grants and donations. This does not cover grants and donations for clinical research.

NO CHANGE

12. INTERACTIONS WITH PATIENT ORGANIZATIONS

NO CHANGE

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.

NO CHANGE

12. INTERACTIONS WITH PATIENT ORGANIZATIONS

12.2 DECLARATION OF INVOLVEMENT

- When working with patient organizations, companies must ensure that the involvement of the company and the nature of that involvement are clear from the outset. No company may require that it be the sole funder of the patient organization or any of its programs.

NO CHANGE

12. INTERACTIONS WITH PATIENT ORGANIZATIONS

12.3 WRITTEN DOCUMENTATION

- Companies that provide financial support or in-kind contribution to patient organizations must have in place written documentation setting out the nature of support, including the purpose of any activity and its funding.

NO CHANGE

12. INTERACTIONS WITH PATIENT ORGANIZATIONS

12.4 EVENTS

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

NO CHANGE

12.5 DISEASE AWARENESS

- **12.5.1 Public Disease Awareness Campaigns**
- The code does not govern Public Disease Awareness Campaigns activities. Member companies may undertake a Public Disease Awareness Campaigns on their own or provide support, sponsor or partner with appropriate medical associations. Whilst not covered by the code, such campaigns must of course comply with local laws, regulations, and/or codes.
- (To be continued...)

CHANGE

12. INTERACTIONS WITH PATIENT ORGANIZATIONS

12.5 DISEASE AWARENESS

- continued
- (12.5.1 Public Disease Awareness Campaigns)

- Such disease awareness campaigns should not be misused as any forms of disguised promotions. Disease education activities may provide information, promote awareness and educate public about health, disease and their management

- (To be continued..)

CHANGE

12. INTERACTIONS WITH PATIENT ORGANIZATIONS

12.5 DISEASE AWARENESS

- *(…continued)* (12.5.1 Public Disease Awareness Campaigns)
-

- All information provided to the public must comply with Article 12 of this Code.
- Activities must not include any reference to a specific prescription product or product brands
- The emphasis of disease education activity should be on the condition and its recognition rather than on the treatment options.
- If discussed, the management options should be presented in a comprehensive, balanced and fair manner.
- Companies must ensure that the venue and locations is appropriate and conducive to informational communication.
- Only company branding is allowed in any items or literature involved in such campaigns. Campaign names, tag line and logos of TA are not allowed.

CHANGE - ADD

12. INTERACTIONS WITH PATIENT ORGANIZATIONS

12.5 DISEASE AWARENESS

- (12.5.2 Disease Awareness Campaigns to HCPs)

- Disease Awareness campaigns to HCPs must not involve any item of independent value/ promotional items/ reminders. However, food and beverage item of not more than RM15.00/item ~~nett each~~ can be distributed to HCPs if tied to disease awareness blitz ~~only~~. Company branding, product branding and tag lines are not allowed on food and beverage items.

NEW

12. INTERACTIONS WITH PATIENT ORGANIZATIONS

12.5 DISEASE AWARENESS

- ~~Member companies may support public disease awareness campaigns by providing support or sponsorship or partnership with appropriate medical associations. Such disease awareness campaigns should not be misused as any forms of disguised promotions. Disease education activities may provide information, promote awareness and educate public about health, disease and their management~~
- ~~All information provided to public must comply with Section 12 of this code.~~

REMOVED

13. RELATIONS WITH THE GENERAL PUBLIC AND LAY COMMUNICATION MEDIA

NO CHANGE

13. RELATIONS WITH THE GENERAL PUBLIC AND LAY COMMUNICATION MEDIA

- **13.1** Request from individual members of the public for information or advice on personal medical matters must always be refused and the inquirer recommended to consult his or her own doctor.
- **13.2** Promotional material issued for distribution or display anywhere to which the public has access must not include any message likely to arouse a demand for all Scheduled Poisons.

NO CHANGE

13. RELATIONS WITH THE GENERAL PUBLIC AND LAY COMMUNICATION MEDIA

- **13.3** Patient education leaflet related to disease condition must be fair, unbiased and not contain any product name and restrict reference to the company providing the leaflet to its name & logo. Therapeutic class/option or chemical name of drug or generic class is allowed, as long as it is unbiased.
- **13.4** Leaflets for instruction in the use of a specific medicine containing reference to the name and illustration of the product must only be provided to the public by a medically qualified practitioner or health care professional.

NO CHANGE

13. RELATIONS WITH THE GENERAL PUBLIC AND LAY COMMUNICATION MEDIA

13.5 USE OF SOCIAL MEDIA COMMUNICATION

- All Social Media Communication for business purposes should be communicated from a Company Profile and not associated to Personal Account.
- All information shared in Social Media for business purposes need to be appropriate, accurate and fair for public viewing and understanding. *(continued…)*

NO CHANGE

13. RELATIONS WITH THE GENERAL PUBLIC AND LAY COMMUNICATION MEDIA

13.5 USE OF SOCIAL MEDIA COMMUNICATION

- *(…continued)*
- 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.
(…continued)

NO CHANGE

13.5 USE OF SOCIAL MEDIA COMMUNICATION

- *(…continued)*
- 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.

NO CHANGE

14. COMPANY PROCEDURES AND RESPONSIBILITIES

NO CHANGE

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 of their activities and materials in that regard.

NO CHANGE

14. COMPANY PROCEDURES AND RESPONSIBILITIES

14.2 MEDICAL REPRESENTATIVES

- •Medical representatives must be adequately trained and possess sufficient medical and technical knowledge to present information on the company's products in an accurate and responsible manner.
- •Medical representatives should at all times maintain a high standard of ethical conduct in the discharge of their duties. They are required to be instructed in and possess a copy of the Code.

NO CHANGE

14. COMPANY PROCEDURES AND RESPONSIBILITIES

14.2 MEDICAL REPRESENTATIVES

- •The requirements of the Code which aims at accuracy, fairness, balance and good taste apply to verbal representations as well as printed material.
- •Medical representatives must not employ any inducement or subterfuge to gain an interview. No payment of a fee should be made for the grant of an interview.
- •A company will assume responsibility, under the Code, for correcting breaches of the Code resulting from misconduct or misrepresentation of fact by any representative.

NO CHANGE

14. COMPANY PROCEDURES AND RESPONSIBILITIES

14.2 MEDICAL REPRESENTATIVES

- •The system of remuneration of representatives should not be such as to adversely influence the proper prescription and usage of pharmaceutical products.
- (The provision relating to remuneration is intended to ensure that no incentives are provided that would lead to unethical behaviour of representatives, and not whether a fixed salary or bonus system is used for compensation.)

NO CHANGE

14. COMPANY PROCEDURES AND RESPONSIBILITIES

14.3 RESPONSIBILITIES FOR APPROVING PROMOTIONAL COMMUNICATIONS

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

NO CHANGE

15. INFRINGEMENT, COMPLAINTS, AND ENFORCEMENT

15. INFRINGEMENT, COMPLAINTS, AND ENFORCEMENT

15.1 COMPLAINTS

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

NO CHANGE

15. INFRINGEMENT, COMPLAINTS, AND ENFORCEMENT

15.2 MEASURES TO ENSURE AND ENFORCE COMPLIANCE

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

NO CHANGE

16. VALID PATENT RIGHTS

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

NO CHANGE

OPERATION OF THE CODE

HIGHLIGHTS

NO CHANGE

OPERATION OF THE CODE
HIGHLIGHTS

- **Highlights of procedures:**
- Initiate contact with the company concerned in order to settle the dispute prior to forwarding the complaint to PhAMA
- There must be proof that the parties concerned have communicated but were unable to come to a decision
- In cases of repeated breaches, the Ethics Committee has the absolute discretion to decide if the case should be considered by the Ethics Review Panel without prior communication between the company concerned
- Definition of repeated breach: Breach of the same section or sections of the code with the same product `claim'.
- A penalty of up to RM100,000.00 will be meted out to repeat offenders.

NO CHANGE

OPERATION OF THE CODE
HIGHLIGHTS

- **Highlights of procedures:**
- Appendix 1: Operation of the Code – Changes to fine value:
- The defendant if found to be in breach will be fined up to RM50,000.00 or up to RM100,000.00"

NO CHANGE

OPERATION OF THE CODE HIGHLIGHTS - PROCEDURE

Level	Description
Pre-official complaint	Company A and Company B to discuss the case prior to any formal complaint to the Ethics Committee, in the endeavour to settle the dispute or disagreement. Engagement must be made within the knowledge of the companies' respective country leads or person of equivalent position. Prior to escalating the matter to PhAMA, the Plaintiff is to provide notification to defendant that it intends to do so after 14 working days from the date of the defendant's receipt of the notification; should no settlement or agreement be reached within the stipulated 14 days' time frame.

NO CHANGE

OPERATION OF THE CODE HIGHLIGHTS-PROCEDURE

Level	Description
Official complaint	Evaluation as to whether there is a case to be deliberated, will be made by the Executive Director upon receipt of the case complaint document. The document will be evaluated to ensure that the complaint logged is within the ambit of the PhAMA Code of Conduct and thus within the jurisdiction of the Ethics Committee to deliberate upon. PhAMA will send a notification of receipt of the complaint documents to the plaintiff, defendant as well as chairperson of the Ethics Committee. All parties in receipt of the notification are to revert to PhAMA with acknowledgement within 7 working days of receipt of the document.

NO CHANGE

OPERATION OF THE CODE
HIGHLIGHTS- PROCEDURE

Level	Description
Ethics Case Review Panel Session	An Ethics Case Review Panel meeting to table and deliberate on the case will be identified by PhAMA based on the availability of chairperson and those who may form a case review panel. PhAMA may invite two persons who are staffs of the company concerned to represent the company during the hearing. Time and duration of representation by the two affected parties will be decided by the case review panel in session, based on the complexity of the case and the amount of information required. Representations, deliberation and decisions made during the hearing sessions should be based on the spirit of the code and not on technicalities. The Ethics Case Review Panel may postpone making any decision should the committee so felt that it requires more time and/or information before deliberating on the case further. Another case review panel meeting may be held thereafter.

NO CHANGE

OPERATION OF THE CODE HIGHLIGHTS- PROCEDURE

Level	Description
Post Ethics Case Review Panel session	Ethics Case Review Panel's decision will be communicated to the plaintiff and the defendant after communication to the Board, for purpose of information only; unless the complexity of the case is as such that the panel requires direction and guidance from the Board, in which case, the matter will be escalated to the Board at its meeting, before proceeding further. Decisions are to be communicated to the plaintiff and defendant within a month of a Case Review Panel's decision. Plaintiff and defendant are to acknowledge receipt of the Case Review Panel decision.

NO CHANGE

QUESTIONS & ANSWERS

Q&A

Data on File

CAN PROMOTIONAL CLAIM REFERENCE MADE TO DATA ON FILE AS LONG AS IT IS REPRODUCIBLE UPON REQUEST?

Yes.

NO CHANGE

Q&A

Brand Names of Other Companies' During CME Events

CAN BRAND NAMES OF PRODUCTS OF OTHER COMPANIES BE USED AS REFERENCES IN CME EVENTS WITHOUT PRIOR CONSENT FROM THE PROPRIETORS?

No. Prior consent from the respective proprietors must be obtain.

NO CHANGE

Q&A

Image of Other Companies' Products During CME Events

CAN THE IMAGE OF A PRODUCT WITHOUT BRAND NAME BE USED AS REFERENCES DURING CME EVENTS WITHOUT PRIOR CONSENT FROM THE PROPRIETOR?

- Even if no brand names of products of other companies are used, the products' images be it capsules, tablets, or medical devices or as such may be so unique that these items may be identifiable to a particular brand. Thus prior consent must also be obtained. This has more to do with the Trade Description Act 2011.

NO CHANGE

Q&A

SAMPLES

MUST PHARMACEUTICAL/SAMPLES REQUESTED/ORDERED BY HEALTHCARE PROFESSIONAL IN PUBLIC HEALTH INSTITUTIONS BE HANDED OVER TO THE HEALTHCARE PROFESSIONAL CONCERNED?

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

NO CHANGE

Q&A

Data Reprints

IS THERE ANY GUIDELINE ON REPRINTS OF DATA ON RISK REDUCTION AND P-VALUES?

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

NO CHANGE

Q&A

Inexpensive Food Items and Drinks in Day to Day Promotional Activities

CAN INEXPENSIVE FOOD ITEMS AND DRINKS AS PER SOCIAL/CULTURAL NORM MAY BE PROVIDED TO HCPS DURING THE COURSE OF DAY TO DAY PROMOTIONAL ACTIVITIES?

- This is not governed by the code. Please refer to your own company's internal guidelines.

CHANGE

Q&A

Distribution of Promotional Item during Disease Awareness Session with Public & HCPs

CAN WE DISTRIBUTE PROMOTIONAL ITEMS DURING OTC - DISEASE AWARENESS SESSIONS?

- This is not governed by the code. Please refer to your own company's internal guidelines.

NEW

CASE STUDIES

CASE STUDIES

Sources

- Adapted from actual cases lodged to PhAMA
- Decision derived from discussion during Ethics Committee meetings and Ethics Panel Review meetings
- Issues raised by members & HCPs

CASE 1

Company requesting specific changes to 3rd party scientific programme

CASE 1: COMPANY REQUESTING SPECIFIC CHANGES TO 3RD PARTY SCIENTIFIC PROGRAMME

- QUESTION
- A pharmaceutical company through the conference secretariat made a request to the scientific committee, for a change of presentation slot so that an already designated presentation slot for an already identified speaker can be filled by the company's own speaker.
- The pharmaceutical company concern in defense claimed that the request was not a form of pressure. Furthermore, the company claimed, such requests is not within the scope of the PhAMA Code of Conduct provisions.

Is this request acceptable?

CASE 1: COMPANY REQUESTING SPECIFIC CHANGES TO 3RD PARTY SCIENTIFIC PROGRAMME

- ANSWER
- Though this incidence is not within the scope of the complaint management process prescribed by the Code, PhAMA does not condone such alleged practices. The stand is as follows:
- Pharmaceutical companies should not interfere in any proceedings related to independent scientific forums. And this includes requests for a particular presentation slot or suggestions to the scientific committee to substitute a company-contracted speaker to speak in lieu of an already independently identified earlier by the organizing committee.

CASE 2

Hospitality offered to HCPs during meetings

CASE 2: HOSPITALITY OFFERED TO HCPS DURING MEETINGS

- Question:
- A company would like to hold a scientific discourse with a particular HCP. The HCP requested that the one hour meeting be held at either the HCP's clinic or at a nearby coffee house.
- Can the company offer hospitality to the HCP if the such scientific discourse is not held at a designated meeting facility e.g. conference venue or even during a formal scientific forum?

CASE 2: HOSPITALITY OFFERED TO HCPS DURING MEETINGS

- Answer:
- The scientific content exchange during such discourse overrides the hospitality offered to the HCPs during such incidences; such incidences may arise due to legitimate reasons e.g. time constraints on the HCPs part.

CASE 3

Scientific event at a renowned tourist area

CASE 3: SCIENTIFIC EVENT AT A RENOWNED TOURIST AREA

- Question:
- Is it acceptable if a 5 star venue located in the vicinity of renowned tourist area, was use for purpose of scientific event. The company in its defense claimed that the venue was specifically requested by the speaker.

CASE 3: SCIENTIFIC EVENT AT A RENOWNED TOURIST AREA

- Answer:
- As long as the scientific event is at least 75% of the total agenda and that the activities during the AGM do not include unwarranted activities like fun fair, lucky draws, etc. It would be acceptable.

CASE 4

Scientific meetings in public area

CASE 4: SCIENTIFIC MEETINGS IN PUBLIC AREA

- Question:
- A company would like to share a latest breakthrough cancer treatment management to a select nurses from a public hospital. However as all the auditorium at the hospital and designated meeting facilities were taken up by other parties, the company held the session at a corner of a coffee house nearby the hospital. The company brought its own LCD projector together with the white screen.
- Is it a concern for a company representatives to have a scientific meeting with HCPs at public area?

CASE 4: SCIENTIFIC MEETINGS IN PUBLIC AREA

- Answer:
- No. However it would be a concern should scientific materials or information be publicly displayed at public venues.

CASE 5

Agenda of a Scientific Event held in Penang

CASE 5: AGENDA OF A SCIENTIFIC EVENT HELD IN PENANG

- Question:
- A company held a 2-day scientific events for HCPs in Penang. Participants to the event arrived in Penang from all over Malaysia around noon on Saturday and departs in the afternoon of Sunday. For the 2-day sponsorship, 5 hours were dedicated to the CME/case studies. Whilst the remaining percentage of time were spent on recreation (dinner, free and easy time). The company claimed that the itenarary for the event was tied to the availability of flights to Penang.
- Is it the programme appropriate? Is the defense argument from the company acceptable?

CASE 5: AGENDA OF A SCIENTIFIC EVENT HELD IN PENANG

- Answer:
- No. The content of the programme is disproportionate. Tying the itinerary to the event is not a defense.

CASE 6

Printed promotional material

CASE 6: PRINTED PROMOTIONAL MATERIAL

- **Question** *(Print on a brochure cover):*
-
- ***TAKE A LOOK***
- ***PRESCRIBE PRODUCT A INSTEAD OF PRODUCT B***
- ***GIVE PATIENTS IMMEDIATE RESULTS***

- Q: Is it a defense if the company concern claims that the wordings should be read separately and not in relation to each other and are thus not disparaging.

CASE 6: PRINTED PROMOTIONAL MATERIAL

- **Answer:**

- The statements should be read in relation to each other. The statement is comparative in nature and also by implication gives the impression that product B is an inferior product and is thus found to be disparaging and has thus breached the PhAMA Code of Conduct.

CASE 7

Disguised Promotion

CASE 7: DISGUISED PROMOTION

Question:

A publisher of a lay magazine is producing a special commemorative edition which will feature the contribution medical breakthrough has on emerging diseases.

Can a company place an advertisement of its related product in the particular edition. According to the publisher, the commemorative edition is only intended for circulation among healthcare professionals only.

CASE 7: DISGUISED PROMOTION

Answer

No. A company may not place any advertisement in a lay press/magazine even if it is intended for circulation among healthcare professionals only as there is no guarantee that the magazine would not be placed in a public area.

It is also a concern that such medium/publications which do not contribute to education in terms of healthcare could be a choice for placing such advertisement.

Such advertisement can only be placed in scientific medical journals/publications which are circulated to healthcare professionals only.

CASE 8

Items of Medical Utility

CASE 8: LOGO ON ITEMS OF MEDICAL UTILITY

Question:

Is it acceptable to print/put the company's logo on any educational materials or items of medical utility? What about brand names?

CASE 8: LOGO ON ITEMS OF MEDICAL UTILITY

Answer

- It is acceptable to print/put the company's logo on any educational materials or items of medical utility.
- Brand names are however not allowed unless if it is for the correct use of product by patients.

CASE 9

GIFTS

CASE 9: GIFTS

- <u>QUESTION:</u>

- 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?

CASE 9: GIFTS

- ANSWER:

- This is not allowed.

THANK YOU