

# **SINGAPORE ASSOCIATION OF PHARMACEUTICAL INDUSTRIES**



## **CODE OF CONDUCT 2022**

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Singapore Association of Pharmaceutical Industries  
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## Table of Contents

<b>SAPI Guiding Principles on Ethical Conduct and Promotion .....</b>	<b>2</b>
<b>Preamble.....</b>	<b>3</b>
<b>1. Scope and Definitions .....</b>	<b>4</b>
<b>2. Basis of Interactions .....</b>	<b>4</b>
<b>3. Pre-Approval Communications and Off-Label Use .....</b>	<b>5</b>
<b>4. Standards of Promotional Information .....</b>	<b>5</b>
<b>5. Printed Promotional Material.....</b>	<b>6</b>
<b>6. Electronic Materials, including Audio Visuals .....</b>	<b>8</b>
<b>7. Interactions with Healthcare Professionals .....</b>	<b>8</b>
<b>8. Samples .....</b>	<b>15</b>
<b>9. Clinical Research and Transparency.....</b>	<b>15</b>
<b>10. Support for Continuing Medical Education .....</b>	<b>15</b>
<b>11. Interactions with Patient Organisations .....</b>	<b>16</b>
<b>12. Communications to the Public .....</b>	<b>16</b>
<b>13. Medical Representatives .....</b>	<b>19</b>
<b>14. Member Company Procedures and Responsibilities .....</b>	<b>20</b>
<b>15. Administration of the Code.....</b>	<b>20</b>
<b>Appendix A .....</b>	<b>25</b>
<b>Appendix A.1 .....</b>	<b>26</b>
<b>Appendix B .....</b>	<b>27</b>
<b>Frequently Asked Questions (FAQs).....</b>	<b>28</b>

## SAPI Guiding Principles on Ethical Conduct and Promotion

Member Companies (defined below) of the Singapore Association of Pharmaceutical Industries (“SAPI”) engage in medical and biopharmaceutical research in order to benefit patients and support high-quality patient care. Member Companies, represented by SAPI promote, sell and distribute their products in an ethical manner and in accordance with all the rules and regulations for medicines and health care.

The following Guiding Principles set out basic standards that form the 2022 SAPI Code of Conduct (the “Code”) which applies to the conduct of Member Companies and their agents, to help ensure that their interactions with stakeholders are appropriate.

1. The health-care and well-being of **patients is the first priority for Member Companies**.
2. Member Companies will conform to high standards of quality, safety and efficacy as determined by regulatory authorities.
3. Member Companies’ **interactions** with stakeholders must at all times be **ethical, appropriate and professional. Nothing should be offered or provided** by a Member Company in a manner or on conditions that would have an inappropriate influence.
4. Member Companies **are responsible for providing accurate, balanced, and scientifically valid** data on products.
5. **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.
6. Member Companies will respect the **privacy and personal information of patients**.
7. **All clinical trials and scientific research sponsored** or supported by Member Companies will be conducted with the intent to develop knowledge that will **benefit patients and advance science and medicine**. Member Companies are committed to the transparency of industry sponsored clinical trials in patients.
8. **Member Companies should adhere to the Code and other applicable industry codes in both the spirit and the letter**. To achieve this, Member Companies will ensure that all relevant personnel are appropriately trained.

# SAPI Code of Conduct

## 2022 Revision

### Preamble

- i. The ethical promotion of prescription medicines is vital to the pharmaceutical industry's mission of helping patients by discovering, developing and promoting new medicines. Ethical promotion helps to ensure that HCPs (defined below) globally have access to information they need, that patients have access to the medicines they need and that medicines are prescribed and used in a manner that provides the maximum healthcare benefit to patients.
- ii. Whereas the Health Products Act (Cap. 122D) provides the main framework for the legal control of the importation, manufacture, distribution and advertising of medicinal products, thereby setting the basic statutory requirements necessary for the protection of the public health, there are areas of activities which, although they may not constitute breaches of the law, they may, by virtue of their unethical nature and, if unrestrained, bring about undue harm to the public health and loss of credibility and respectability for the pharmaceutical industry.
- iii. The Code established by the SAPI with the approval of its members, provides guidance for the proper conduct in the marketing and promotion of medicinal products and serves as the basis for self-discipline within the industry. This includes any activity undertaken by any Member Company or distributors that promote the prescription, supply, sale, or distribution of Pharmaceutical Products (defined below), including vaccines.
- iv. SAPI member companies and anyone acting on their behalf must comply directly with the SAPI Code of Conduct.
- v. The Code includes standards for the ethical promotion of Pharmaceutical Products to HCPs and helps ensure that Member Companies' interactions with HCPs and other stakeholders, such as Medical Institutions (defined below) and Patient Organisations (defined below), are appropriate and perceived as such.
- vi. The Code, which is in keeping with the spirit of the revised [Code of Practice of the International Federation of Pharmaceutical Manufacturers Associations \("IFPMA"\) 2019](#), is administered by the Ethics & Business Integrity Committee appointed by the Board of Directors. Acceptance and active observance of the Code are mandatory for membership with SAPI. In 2019 IFPMA (International Federation of Pharmaceutical Manufacturers & Associations) adopted [new Ethos](#). Accordingly, SAPI, fully shares the new values and principles that are given in IFPMA's new Ethos.

# The SAPI Code

## 1. Scope and Definitions

### 1.1 Scope

The Code covers interactions with HCPs, Medical Institutions and Patient Organisations, and the Promotion of Pharmaceutical Products. Where direct promotion to the public is allowed, this is covered by local laws, regulations and/or relevant codes of practice. Member Companies should of course, comply with these local laws, regulations and/or codes.

In all matters of application, interpretation and enforcement of any Article (defined below) of the Code, it is to be understood that compliance with Singapore laws, regulations and regulatory decisions and requirements will take precedence.

### 1.2 Definitions

For the purposes of the Code:

**“Article”** means an article in this Code.

**“Healthcare Professional” (“HCP”)** 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.

**“Medical Institution”** means typically an organisation that comprises of HCPs and/or that provides healthcare or conducts healthcare research.

**“Member Company”** means any company or other entity or organisation that is a member of SAPI.

**“Patient Organisation”** means typically a not-for-profit institution that primarily represent the interests and needs of patients, their families and and/or caregivers.

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

**“Promotion”** means any activity undertaken, organised or sponsored by a Member Company which is directed at HCPs to promote the prescription, recommendation, supply, administration or consumption of its Pharmaceutical Product(s) through all methods of communications, including the internet. Promotion of over-the-counter products (**“OTC Products”**) directed to HCPs are within the scope of the Code. Promotion of products for infant nutrition, diagnostic tests, surgical and medical devices and OTC Products directed to consumers are not included in the scope of the Code.

## 2. Basis of Interactions

### 2.1 Basis of Interactions

Member Companies’ relationships with HCPs and other stakeholders are intended to benefit patients and to enhance the practice of medicine. Interactions should be focused on informing HCPs about medicines, providing scientific and educational information and supporting medical research and education.

### 2.2 Transparency of Promotion

Material relating to Pharmaceutical Products and their uses, whether promotional in nature or not, which is sponsored by a Member Company, should clearly indicate by whom it has been sponsored. Promotion should not be disguised.

### **3. Pre-Approval Communications and Off-Label Use**

- 3.1** No Pharmaceutical Product shall be promoted for use in Singapore until the requisite approval for marketing for such use has been given by the Health Sciences Authority, Singapore
- 3.2** This provision is not intended to prevent the right of the scientific community and the public to be fully informed concerning scientific and medical progress. It is not intended to restrict a full and proper exchange of scientific information concerning a Pharmaceutical Product, including appropriate dissemination of investigational findings in scientific or lay communications media and at scientific conferences. Nor should it restrict public disclosure of information to stakeholders and others concerning any Pharmaceutical Product, as may be required or desirable under law, rule or regulation.
- 3.3** Only Medical Departments of our Member Companies will respond to unsolicited queries pertaining to pre-approved label use.
- 3.4** At international scientific meetings held in Singapore, where a significant number of attendees are from outside of Singapore, advertising of locally unapproved products/ indications may be acceptable.
- 3.5** When such advertising is undertaken, material should clearly indicate that the product is not locally approved.

### **4. Standards of Promotional Information**

#### **4.1 Consistency of Product Information**

It is understood that national laws and regulations usually dictate the format and content of the product information communicated on labelling, packaging, leaflets, data sheets and in all promotional material. Promotion should not be inconsistent with locally approved product information.

#### **4.2** In general, Member Companies should ensure that all Promotion complies with the following:

- 4.2.1** Member Companies are responsible to ensure compliance with the Code;
- 4.2.2** Data are substantiated;
- 4.2.3** False or misleading claims are not made;
- 4.2.4** Unapproved products and indications are not promoted;
- 4.2.5** The material and data are presented in good taste;
- 4.2.6** Unqualified superlatives are not allowed;
- 4.2.7** New products are clearly identified;
- 4.2.8** Comparative statements must be used carefully;
- 4.2.9** Imitation that may give rise to confusion is not allowed;
- 4.2.10** Medical ethics is adhered to; and

- 4.2.11** Distinction of promotional material is clearly defined
- 4.3** Data from in vitro and animal tests should be clearly marked as such, and not be cited in such a way that it could give an incorrect or misleading impression
- 4.4 Substantiation**
- Promotion should be capable of substantiation either by reference to the approved labelling or by scientific evidence. Such evidence should be made available on request to HCPs. Member 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.
- 4.5 Opinions**
- The medical and scientific opinions of opinion leaders and health professionals, and products, activities or representatives of other pharmaceutical companies must not be disparaged.
- 5. Printed Promotional Material**
- 5.1** Where local regulations are in force, which define requirements, these take precedence.
- 5.2** Printed promotional material shall be presented in a legible manner. The scientific basis and presentation of the product information must be in conformity with the general principles set out in **Article 4** and where applicable, with the authorised product information.
- 5.3** Promotional material such as mailings and journal advertisements and loose inserts must not be designed to disguise its real nature.
- 5.4** Advertisements in journals should not be designed so as to resemble editorial material.
- 5.5** Promotional material should conform, both in text and illustration, to canons of good taste and should recognise the professional standing of the recipient.
- 5.6** Representation of the nude adult human form or partly clothed figures, should not be used in promotional material in such a way as to arouse a visual or emotional response in order to attract attention to the text. Displays of part of the naked body which are necessary to illustrate pictorially the message of the text are permissible, provided that they conform to the dictates of decency and good taste.
- 5.7** Material and articles from the lay press should not be used as promotional material.
- 5.8** 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.
- 5.9** 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.
- 5.10** Graphs 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.
- 5.11 Reprints, abstracts and quotations in print or other media**
- 5.11.1** Such 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 highlighting or underlining to give prominence to selected portions of the material).

- 5.11.2** 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.

## **5.12 All Advertisements**

- 5.12.1** All advertisements appearing in print must include:

- i. the name of the product (normally the brand name);
- ii. the active ingredients, using an approved name where one exists (i.e. International Non-proprietary Name (“**INN**”)); and
- iii. the name and address of the Member Company or its agent responsible for marketing the product.

- 5.12.2** The mailing address of the contact from which further information may be obtained must appear, either in the advertisement itself or be readily accessible from the publication in which the advertisement appears.

## **5.13 Full Advertisements**

Full advertisements are those which include promotional claims for the use of the products. In addition to the requirements of **Article 5.12**, full advertisements must also include prescribing information in the form of:

- 5.13.1** Health Sciences Authority approved indication or indications for use together with the dosage and method of use;
- 5.13.2** a succinct statement of the contraindications, precautions and side effects;
- 5.13.3** any locally obligated warnings relating to the product;
- 5.13.4** a statement that full prescribing information is available on request;
- 5.13.5** the name and address of the local operating unit or the address from which full information can be obtained;
- 5.13.6** in cases where journal advertisements and prescribing information are separated, it must be clear where in the journal the prescribing information can be found;
- 5.13.7** journal advertisements must be of sufficient size to ensure that all wording is legible; and
- 5.13.8** the word "new" should not be used to describe products that have been available in a specific market for more than 12 months.
- 5.13.9** Companies can also fulfil sections 5.13.1 to 5.13.4 by providing an electronic link (e.g. URL, QR code or data matrix) to the full prescribing information via a platform that is compliant with the Health Products Act (Advertisement of Therapeutic Products) Regulations 2016.

## **5.14 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, prescribing information referred to in **Article 5.13** may be omitted.



## **6. Electronic Materials, including Audio Visuals**

**6.1** The same requirements shall apply to electronic promotional materials as apply to printed materials. Specifically, in the case of Pharmaceutical Product related websites:

- 6.1.1** the identity of the Member Company and of the intended audience should be readily apparent;
- 6.1.2** the content should be appropriate for the intended audience;
- 6.1.3** the presentation (content, links, etc.) should be appropriate and apparent to the intended audience; and
- 6.1.4** country-specific information should comply with local laws and regulations.

## **7. Interactions with Healthcare Professionals**

### **7.1 Events**

#### **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 HCPs organised or sponsored by a Member Company should be to provide scientific or educational information and/or inform HCPs about products.

#### **7.1.2 Events Involving Foreign Travel**

Events that comprise participants from different countries are therefore justified and permitted to be hosted in any of the countries that are represented by the delegate.

#### **7.1.3 Promotional Information at Events**

Promotional information which appears on exhibition stands or is distributed to participants at international scientific congresses and symposia may refer to Pharmaceutical Products which are not registered in the country where the Event takes place, or which are registered under different conditions, provided that the following conditions are observed:

- i. Host country regulations should permit such an arrangement;
- ii. The Event should be an international and scientific Event with a significant proportion of the speakers and attendees from countries other than the country where the Event takes place;
- iii. Promotional material (excluding promotional aids as described under **Article 7.5.2**) for a Pharmaceutical Product not registered in the country of the Event should be accompanied by a suitable statement indicating the countries in which the product is registered and make clear that such product is not available locally;
- iv. Promotional material which refers to the prescribing information (e.g. indications, warnings, etc.) authorised in a country or countries other than that in which the Event takes place but where the product is also registered, should be accompanied by an explanatory statement indicating that registration conditions differ internationally; and
- v. An explanatory statement should identify the countries in which the product is registered and make it clear that it is not available locally.

#### **7.1.4 Appropriate Venue**

Member Companies may initiate, hold, organise or sponsor a wide range of Events. All Events must be held in an appropriate venue that is conducive to the scientific or educational objectives and the purpose of the Event.

With any Event, certain basic principles shall apply:-

- i. The primary objective of the Event must serve to enhance medical knowledge and improve the quality use of medicine in Singapore;
- ii. The Event must have a clear educational and/or scientific content. Objective evidence of the educational value of the Event is required (e.g. agenda or scientific program) that clearly states the educational purposes, content, start and finish times and duration of the Events. Member Companies should undertake to review the educational value and venue, prior to agreeing to organise or sponsor an Event;
- iii. Any venue must be appropriate and conducive to the scientific or educational purpose of the Event. Lavish or extravagant venues must not be used; and Member Companies must avoid venues that are renowned for their leisure and entertainment facilities. The choice of venue must also be able to withstand public and professional scrutiny and comply with professional and community standards of ethics and compliance; and
- iv. In determining whether such an Event is acceptable or not, consideration must also be given to the overall cost, facilities offered by the venue, nature of the audience, associated activities (e.g. hospitality, subsistence provided) and the like. As with any Event, it should be the program that attracts delegates and not the associated hospitality or venue.

#### **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.

Providing hospitality in relation to food and drinks as per social/cultural norms in a local setting to members of the medical and allied professions should be limited to less than S\$120 per person per meal. This is applicable to Singapore only and excludes GST and Service Charge. However, this should be accompanied with dissemination of scientific or educational information.

- 7.1.6** No stand-alone entertainment or other leisure or social activities may be provided or paid for by Member Companies. However, entertainment of a modest nature which is secondary to refreshments and/or meals is allowed during Events.

### **7.2 Sponsorship**

- 7.2.1** The Code recognises the contribution of the pharmaceutical industry to the quality use of medicines in Singapore through sponsorship of HCP to attend local and international Events.

- 7.2.2** Sponsorship of HCPs must always be relevant to the practice of the HCPs and in line with the primary objective of upgrading scientific and clinical knowledge and improving the

quality use of medicines in Singapore. These activities may be broadly categorised under Third Party Educational Events (**Article 7.2.4**) and Company Standalone Events (**Article 7.2.5**).

**7.2.3** Member Companies may sponsor HCPs to attend Events, provided such sponsorship is in accordance with the following requirements:

- i. The Event complies with the requirements in the Code as described in **Article 7.1**;
- ii. The Event is primarily dedicated, in both time and effort, to objective scientific and educational activities;
- iii. Sponsorship may be provided to a HCP to attend an Event provided the Event is directly related to the HCP's area of expertise;
- iv. Sponsorship must not be conditional upon any obligation by the HCP to recommend, prescribe, dispense, purchase, supply or administer or promote a Member Company's product(s). Nothing should be offered or provided in a manner, or on conditions, that would interfere with the independence of a HCP's professional practice;
- v. Where Member Companies undertake the sponsorship of a HCP such sponsorship must:
  - have a fair and independent selection process and not give any potential appearance of inappropriateness or bias, and avoid any issue of conflict of interest;
  - conform to applicable laws, professional and community standards of ethics and good taste; and
  - enhance the quality use of medicines.
- vi. Where applicable, all Member Companies and their affiliates should only provide economy class tickets for air travel of less than 6 hours. This should apply to all faculty members (e.g. speakers, members of Advisory Boards as well as attendees);
- vii. No payments may be made to compensate HCP for time spent in attending the Event;
- viii. Any activities that have an element of chance should not be part of the Event; and
- ix. When a congress/symposium is organised, a minimum of 75 per cent of time should be spent on core activities of the congress/symposium and a maximum of 25 per cent of time devoted to hospitality, entertainment activities in relation to food and drinks limited to entertainment of modest nature which is secondary to refreshments and/or meals.

**7.2.4 Third Party Educational Events**

- i. A "**Third Party Educational Event**" is any scientific conference, professional program, meeting or event sponsored or conducted by a third party medical association, including but not limited to, events of an educational or scientific or policy-making nature and for the purpose of promoting scientific knowledge, medical advancement or delivery of effective healthcare.

- ii. Member Companies may support such Third Party Educational Events through sponsorships to hospitals, medical associations and independent professional bodies (collectively “**Organisers**”) to support individual HCP’s attendance at the event as delegates, subject to the following conditions:
- (a) The support preserves the independence of medical education and any such sponsorship provided to Organisers must not be conditional upon any obligation to prescribe, recommend, purchase, supply, administer or promote any Pharmaceutical Product;
  - (b) As far as possible, industry sponsorship should be objectively disbursed and managed by the applicable governing hospitals, medical associations and independent professional bodies;
  - (c) Sponsorships may be made either following a written offer by the Member Company, or a request for support from the Organisers, including sufficient information to allow Member Companies to evaluate the scientific and educational merit of the event as well as the appropriateness of the venue and agenda;
  - (d) Sponsorship funding provided is proportionate to the overall costs of the event;
  - (e) The event agenda is detailed and does not include standalone entertainment, side trips, or other inappropriate activities, and the venue complies **with Article 7.1.4**;
  - (f) The support is consistent with relevant guidelines established by the Organiser and any accrediting body;
  - (g) The Organiser independently controls and is responsible for the selection of program content, faculty, educational methods and materials;
  - (h) Member Companies must not offer or directly pay for, or reimburse, the expenses of any individual HCP delegates to attend the event and the sponsorship must not inappropriately benefit any individual HCP or provide for any private side trips, recreation, entertainment or lavish meals and accommodation;
  - (i) Member Companies must not directly and/or indirectly select or influence the selection of any HCPs to attend the event. All HCPs from both the public and private sectors should be independently selected by a decision making committee, independent professional body or medical association whereby selection criteria and processes are legitimate;
  - (j) No Member Company or any representative/agent acting on its behalf may make registration, accommodation and/or travel arrangements for any attending individual HCP. Payment of any sponsorship must be paid only to the Organisers;
  - (k) All sponsorship arrangements must be appropriately documented before and after the Third Party Educational Event. It is recommended that Member Companies collaborate with the Organisers to put in place monitoring processes for the proper disbursement of sponsorship in accordance with the Code; and

- (i) Meals and refreshments provided to HCPs by Member Companies in connection with a Third Party Educational Event must comply with **Article 7.1**.

#### **7.2.5 Company Standalone Events**

A “**Company Standalone Event**” is any educational conference, professional program, meeting or event for the enhancement of medical knowledge, drug experience and the quality use of medicines, which is sponsored or conducted by a Member Company. Company Standalone Events are important for the dissemination of knowledge and experience to HCPs. The primary purpose of an educational meeting under this category must be the enhancement of medical knowledge, drug experience and the quality use of medicines. Objective evidence of the educational value of the Company Standalone Events is required (i.e. an invitation or agenda that clearly describes the educational purpose, content, start and finish times and duration of Company Standalone Events).

- i. Member Companies may provide or support Company Standalone Events for HCPs in appropriate venues within Singapore to advance the standards of healthcare and must have the primary objective of enhancing medical knowledge and improving the quality use of medicines in Singapore.
- ii. Member Companies must not organise or sponsor Company Standalone Events for HCPs that take place outside of Singapore where the majority (i.e. more than 51%) of the attendees are Singapore residents.
- iii. Due to regional clustering and efficiencies, Member Companies may support regional Company Standalone Events held outside of Singapore and may directly facilitate HCP’s attendance including arrangement of reasonable travel and accommodation support.
- iv. A Member Company may sponsor Company Standalone Events which are in-hospital/institutional, such as journal clubs, grand rounds, multidisciplinary and in-service meetings held within the HCP’s workplace. To qualify for sponsorship, the primary purpose of the Company Standalone Event must be the provision of medical education. Sponsorship of Company Standalone Events which are in-hospital/institutional but lack medical education are therefore not permitted.
- v. Company Standalone Events must comply with meals limits, venue appropriateness.

### **7.3 Guests**

Member Companies should not pay any costs associated with individuals accompanying invited HCPs.

### **7.4 Fees for Services**

HCPs may be engaged as consultants and advisors for services such as speaking at and/or chairing Events, involvement in medical/scientific studies, clinical trials or training services, participation at advisory board meetings, and participation in market research where such participation involves remuneration. The arrangements which cover these genuine consultancies or other services must, to the extent relevant to the particular arrangement, fulfil all the following criteria:

- 7.4.1** 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;

- 7.4.2 a legitimate need for the services must be clearly identified and documented in advance;
  - 7.4.3 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;
  - 7.4.4 the number of consultants retained must not be greater than the number reasonably necessary to achieve the identified need;
  - 7.4.5 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
  - 7.4.6 the compensation for the services must be reasonable and reflect the fair market value of the services provided.
- 7.5 Gifts and Other Items**
- 7.5.1 Prohibition of Cash & Personal Gifts**
- Items in this section, where permissible, must never constitute an inducement to prescribe, recommend purchase, supply, sell or administer a pharmaceutical product. Prohibition only applies to prescription medicines.
- Payments in cash or cash equivalents (such as gift certificate), gifts for the personal benefit of the HCPs (such as sporting or entertainment tickets, electronics items, etc.) and cultural courtesy gifts (such as mooncakes, cookies, mandarin oranges, etc.) either directly or through clinics and institutions or any other third parties must not be provided/offered to HCPs.
- Participation or any support in the form of financial donation and /or gifts to medical societies, hospitals or a clinic's social events including Annual General Meeting, Sports Day, Family Day, Annual Dinner etc. are not allowed.
- 7.5.2 Gifts**
- i. A promotional aid (commonly known as gimmick or branding item such as sticky notes, note pads, calendars) is a non-monetary item given for a promotional purpose, but does not include promotional materials or detailing aid as defined in Section 5. Providing or offering such promotional aid to HCPs in relation to the promotion of prescription-only medicines is prohibited.
  - ii. However, pens and notepads may be provided to HCPs in the context of company organized events for the purpose of taking notes provided these are company branded only (no product branding), of minimal value and only the necessary quantity are distributed.
  - iii. Promotional aids in minimal quantity valued at no more than S\$20 may be provided or offered to HCPs solely for the promotion of pharmacy only medicines and over-the-counter medicines if relevant to the practice of the HCP.
  - iv. Congratulatory or condolence flowers and messages in any form of media directly to or on behalf of a HCP or a Centre are strictly prohibited.
  - v. Food items and drinks as a part of discussion may be provided to HCPs during the course of day to day promotional activities only and should be limited to less than S\$20 per HCP.
- 7.5.3 Items of Medical Utility to enhance Provision of Medical Services and Patient Care**

- i. Both educational materials and items of medical utility should not be offered on more than an occasional basis (i.e. not more than 2 occasions per HCP per year), even if each individual item is appropriate. Items of medical utility are items that:
  - (a) are intended for the direct education of HCPs and/or patients and are beneficial to enhancing the provision of medical services and for patient care in a clinical setting; and
  - (b) do not have value to HCPs outside of the scope of their practice and educational need.
  - (c) 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.
- ii. Items of medical utility may be offered or provided by member companies free of charge if such items are of modest value, do not offset and/or subsidise routine business expenses that a HCP might otherwise incur and the value of such items should be limited to less than S\$200 per item.
- iii. Medical related text or reference books/information, subscription to on-line journals (healthcare or biomedical journals only) and other educational materials may be given to HCPs if they serve a genuine educational function that is relevant to their field of practice, but subject to the following limits:
  - (a) Private Specialists/General Practitioners/Public Hospital Doctors – less than S\$1000 per HCP per year.
  - (b) Public Hospitals and Private Medical Centres/Hospitals – less than S\$1,000 per Clinical Department in a Public Hospital/Private Medical Centre/Private Hospital per year.

#### 7.5.4 Donations

Member Companies may provide monetary, used items or product donations strictly for charitable purposes and charitable organisations if they are:

- from an institution or organisation, not an individual HCP;
- substantiated by written documentation of details of donation request and **reasonable and justified** in the light of the activity being funded;
- able to withstand public scrutiny and given without the intent to receive any benefit in exchange.

#### 7.5.5 Independent Grants

Member Companies can provide independent grants towards financial support for medical/scientific research, education, policy initiatives and patient advocacy related activities, if they are:

- Unsolicited;
- from an institution or organisation, not an individual HCP;
- unrelated to the prescribing, purchasing, registration of any products;
- substantiated by written documentation of details of program;
- legitimate and reasonable in consideration of the program being supported or funded, and the supporting **expenses properly accounted for**;

- able to withstand public scrutiny.

## **8. Samples**

- 8.1** Giving away of 'samples' as an inducement to purchase is prohibited. Reasonable quantities of samples (including patient starter packs), clearly identified as such, may be supplied to the prescribing professions to familiarise them with the products, to enable them to gain experience with the product in their practice, or upon request. Samples should not be sold.
- 8.2** Samples must not be used for clinical studies.
- 8.3** Where samples of products restricted by law to supply on prescription are distributed by a representative, the sample must be handed directly to the doctor or given to a person authorised to receive the sample on his behalf.
- 8.4** Member Companies should have adequate systems of control and accountability for samples provided to HCPs including how to look after such samples whilst they are in possession of medical representatives.

## **9. Clinical Research and Transparency**

### **9.1 Transparency**

Member Companies are committed to the transparency of clinical trials which they sponsor. It is recognised that there are important public health benefits associated with making clinical trial information more publicly available to HCPs, patients, and others. Such disclosure, however, must maintain protections 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**

- 10.1** CME helps ensure that HCPs 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 Member Companies is appropriate.
- 10.2** When Member 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 recognised opinions. Content must consist of medical, scientific or other information that can contribute to enhancing patient care
- 10.3** Member Companies must follow Article 7 where applicable.



## **11. Interactions with Patient Organisations**

### **11.1 Scope**

The pharmaceutical industry has many common interests with Patient Organisations. All interactions with Patient Organisations must be ethical. The independence of Patient Organisations must be respected.

### **11.2 Declaration of Involvement**

When working with Patient Organisations, Member Companies must ensure that the involvement of the Member Company and the nature of that involvement are clear from the outset. No Member Company may require that it be the sole funder of the Patient Organisation or any of its programs.

### **11.3 Written Documentation**

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

### **11.4 Events**

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

## **12. Communications to the Public**

### **12.1 Introduction**

- 12.1.1 Where it is permitted by law to communicate directly with patients regarding their prescription medicines, all such information should be accurate, fair and not misleading.
- 12.1.2 Communications to the public may include the provision of patient package inserts and other leaflets and booklets, etc., made available to inform patients about products prescribed by health professionals.
- 12.1.3 Request from individual members of the public for information or advice on personal medical matters, including about the product which has been prescribed, should be redirected to his or her own doctor.

### **12.2 Disease Awareness Programs**

#### **12.2.1 General**

- A. A Disease Awareness Program is defined as information presented in a manner to educate and inform consumers on one or more types of diseases or medical conditions or treatments of such, for the purpose of raising public awareness and knowledge of such diseases, conditions or treatments.
- B. Member companies may undertake public disease awareness programs on their own or provide support, sponsor or partner with appropriate organizations including but not limited to medical associations or institutions patient advocacy groups, NGOs, or schools.

- C. Where Member Companies assist in the conduct of public/patient disease awareness programs providing information on, signs and symptoms of medical conditions, illnesses, and available treatments, such activities must comply with local laws, guidelines, regulations, and/or codes.
- D. Disease Awareness Programs should not be constructed as indirect advertisements of therapeutic products. Publication of such advertisements, whether directly or indirectly, in the form of a Disease Awareness Program, is an infringement of the relevant laws (e.g., HSA Health Products Act 2016), and the person and publisher, who are found guilty, may be subjected to the punitive measures as prescribed in the law.

#### 12.2.2 Scope

- A. Disease awareness programs can comprise a broad range of education methods delivered across varied settings, such as:
  - campaigns
  - seminars and webinars
  - workshops, courses and other face-to-face education
  - audio-visual education material
  - online education resources including downloadable materials
  - community-level resources such as flyers, posters, and booklets
- B. Disease awareness programs and activities often involve diseases or conditions that require diagnosis, monitoring, treatment or management by a health care professional.

#### 12.2.3 Guidelines

- A. The emphasis of the educational information should be on the condition and its recognition rather than on the treatment options. The information should be accurate, up-to-date, substantiable, comprehensive, balanced and fair, readable/accessible and source-identified.
- B. The appropriate treatment for an individual patient is for the healthcare professional to decide, in consultation with the patient, and this should be clearly stated. While a disease awareness program may make reference to a range of treatment options, if it is likely to encourage the public to seek information on a particular product, or seek prescription for a particular medicine, then it may be considered an advertisement
- C. The tone of the material or information must not be presented in a way that unnecessarily causes alarm or misunderstanding in the community, nor stimulate the demand for prescription of a specific product. Any materials created should be designed to convey key messages, supported by appropriate design and formatting without using colours or indirect references to therapeutic products.
- D. If material, which on face value appears to be disease education, provides links to additional resources or alternate information (including websites or endorsements) which would have the effect of promoting a specific prescription product, then the originating material would be considered to be advertising.
- E. For disease awareness activities where there are limited treatment options (where there is only one, or leading option of few medicinal treatments available to treat or diagnose the specific disease, or where a new medicinal product has just been released for the treatment or diagnosis of the disease state), as the information may draw attention to one specific prescription medicine or product, member companies are to ensure that the activities and emphasis of information is focused on health and disease education, with details on where to get appropriate advice such as speaking to a healthcare professional.

## 12.3 Media Communications

### 12.3.1 Press Release

- A. Information in press releases should be factual, non-promotional and not be used as a mechanism to promote a therapeutic product.
- B. Factual information about a therapeutic product e.g. mechanism of action, approved intended uses (indications), benefit-risk profile may be provided to the media community through press releases.
- C. Information relating to the therapeutic product must be substantiated by objective evidence and aligned with the approved intended purposes. Prior approval by Health Sciences Authority is not required for press releases.
- D. For more information on the prescribed requirements, please refer to the relevant laws and regulations, e.g. [Health Products \(Advertisement of Therapeutic Products\) Regulations 2016](#).

### 12.3.2 Advertorials / Paid Media

- A. General media articles concerning specific therapeutic products must not be initiated by companies. However, information on medical conditions is allowed. Companies should not attempt to encourage the publication of general media articles or their content with the aim of promoting their products.

### 12.3.3 Social Media

- 12.3.3.1 Social media means any form of online channel, providing the potential for two-way interaction between two parties, even if this functionality is disabled on a given page. Social media may be provided for use by either HCPs and/or consumers. Member Companies should develop an internal policy that defines its rules and procedures for company employees' use of social media that makes reference to the company or the company's business, products (including branding and taglines), people, policies, relationships and competitors, including personal use of social media that references a company's interests.

(Explanatory note for 12.3.3.1: Examples of social media include (but are not limited to): Facebook, YouTube, LinkedIn, Instagram and Twitter.)

- 12.3.3.2. Companies are responsible for all content and activities on company-owned social media pages. User-generated content that a company chooses to keep on a site, or extracts from one site and places on another site, is the responsibility of the company and must be held in accordance with relevant laws. Company-owned pages should provide a statement that defines the circumstances under which user-generated content will be removed.

- 12.3.3.3. Companies must comply with the requirements of the Code and not post content which:

- does not conform to community standards of ethics and good taste;
- relates to unregistered products or indications;
- is inappropriate;
- may be considered false or misleading;
- is in breach of any laws or regulations of Singapore; and
- may represent a patient testimonial or HCP endorsement of a product and that may be viewed or accessed by the general public. User-generated posts on company-owned social media pages that do not comply with the above should be removed as soon as discovered (or at least within 1 business day) of posting.

- 12.3.3.4. Any activity on a social media site by a company employee, or an agent acting on the company's behalf in relation to prescription medicines, must comply with this Code. Company employees or agents who are active on a social media site and who are present on behalf of the company must identify themselves as such.

- 12.3.3.5. Personal use of social media by a company employee that potentially identifies them as a company employee (e.g. LinkedIn), or that otherwise references their employer's interests, may

be perceived as advertising or promotion of a product. Any social media activity that may be reasonably perceived as such, must be accurate, truthful and comply with this Code. Content must conform to community standards of ethics and good taste. A disclaimer that the views expressed are the company employees own and not those of his or her employer, does not exempt the company employee from this requirement.

#### 12.3.4 Websites

##### A. Linking to Third Party Content

Member companies are advised (as part of its internal approval process), whether or not an express permission to link to any third-party content is required. When linking to third party content:

- The linked content must comply with all applicable laws and regulations of Singapore.
- Ensure the linked content is credible (i.e. substantiated by established facts) and aligns well with the member company's values, tone and objectives.
- Clarify that the linked content belongs to a third-party by including an appropriate citation or link back to the original source.
- Ensure there is no implication that linked non-sponsored third-party content is affiliated with or endorsed by the member company.

##### B. Where Company-controlled websites reference and/or link to other external information sources or internet sites, the Company is accountable for ensuring that these information sources and internet sites are appropriate and will enhance appropriate disease condition knowledge which adhere to applicable Singapore laws and/or regulations.

##### C. For materials hosted online that include promotional claims, whether hosted by a Company or a third party, a restrictive mechanism such as password protection for system entry is consistent with ensuring online promotional content is only available to healthcare professionals.

## 13. Medical Representatives

### 13.1 Training and Responsibilities

**13.1.1** Medical representatives must be adequately trained and possess sufficient medical and technical knowledge to present information on their Member Company's products in an accurate, responsible and ethical manner. They must also feed back to the Member Company, from contacts in the medical and allied professions, information which they receive on the use of products and particularly reports of side effects.

**13.1.2** The training given to medical representative should be an on-going process and should include familiarity with SAPI and IFPMA Codes of practices. The Certified Medical Representative ("CMR") awarded by SAPI is one of the qualifications for Medical Representatives in Singapore.

**13.1.3** It is the onus of the Member Company to familiarise all employees of the sales, marketing, regulatory, medical or such areas related to the principles of the Code and practices of SAPI and of local legislation.

**13.1.4** Medical representatives should ensure that the frequency, timing and duration of calls, together with the manner in which they are made, are such as not to cause inconvenience to the HCP. The wishes of an individual HCP, or the arrangements in force at any particular establishment, must be observed by medical representatives.

### 13.2 Member Company Responsibility

A Member Company will assume the responsibility, under the Code, for correcting breaches of the Code resulting from misconduct or misrepresentation of facts by any representative.

### **13.3 Remuneration**

The system of remuneration of representatives should not be such as to adversely influence the proper prescribing of Pharmaceutical Products by the physician. The provision relating to remuneration is intended to ensure that no incentives are provided that would lead to unethical behaviour of representatives, and not whether a fixed salary or bonus system is used for compensation.

## **14. Member Company Procedures and Responsibilities**

### **14.1 Procedures**

Member 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.

### **14.2 Training**

Member Companies should also ensure that relevant employees receive training appropriate to their role.

### **14.3 Responsibilities for Approving Promotional Communications**

**14.3.1** A designated Member 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.

**14.3.2** Date of first use of all promotional materials circulated to the market shall not be more than two (2) years from the date of approval. Any materials used beyond this point must be re-approved. Henceforth, all published promotional materials shall be dated and updated regularly. Thus, date of print must be defined on document.

**14.3.3** A register, the approval folder and a sample of each approved item must be maintained locally for a minimum of two (2) years.

## **15. Administration of the Code**

### **15.1 Submission of Complaint**

**15.1.1** Member Companies that are involved in any dispute should treat that any complaint to the Ethics & Business Integrity Committee is a last resort action to resolve the issue after they have exhausted all reasonable avenues, including contacts between the CEOs of both Member Companies, to resolve it amicably. All complaints on breach of the Code, must be made in writing and submitted by the CEO of the complainant Member Company (in order that the CEO of that Member Company is aware that a complaint has been submitted) together with a processing fee of S\$1,500.00 to SAPI. It will first be validated to ensure that:

- i. It appears to be a genuine matter, submitted in good faith. A documentation to show that there has been a communication between the CEOs of the involved parties, to show that all parties have tried to resolve the issue amicably.

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

**15.1.2** The minimum information required is:

i. **Source of the complaint**

The complaint letter must come with the Member Company's letterhead.

ii. **Member Company**

For each case in the complaint, the identity of the Member Company which is alleged to be in breach of the Code and the name of any product / marketing activities which are specifically involved.

iii. **Reference material**

For each case, a specific reference to the source of the advertisement/activity which is the subject of the complaint of printed material or other evidence.

iv. **Date**

The date of the alleged breach of the Code.

v. **Summary**

For each case, brief description of the complaint with a specific reference to the part of the Code under which the complaint is being made (i.e. Article number)

**15.1.3** All complaints of breaches of the Code against Member Companies must be sent directly to SAPI instead of through third parties, e.g. Health Sciences Authority, Ministry of Health. If a complaint against a Member Company is referred or re-directed to SAPI by any third party, the complaining Member Company must pay the applicable processing fee to SAPI to review the complaint.

**15.1.4** Externally generated complaints from doctors, pharmacists or members of the public against any Member Company will be dealt with in the same manner as if they came from a Member Company, except that no processing fee will be levied on the complainant.

**15.2 Ethics & Business Integrity Committee Members**

**15.2.1** The Ethics & Business Integrity Review Committee ("**EBIC**") for the review of any complaint shall consist of at least 50% of the EBIC voting members, subject to a minimum of 5 members and 1 secretariat staff. The EBIC members are unique for each case, to prevent any lack of quorum if there is a conflict of interest.

**15.2.2** If there is a lack of quorum due to the members being the affected parties in the complaint, the EBIC can call upon any member that the EBIC deems suitable, to serve under the EBIC for a particular case.

**15.2.3** The secretariat staff is the Executive Director of SAPI and will not have the voting rights.

**15.3 Review Procedures**

**15.3.1** Any complaint against a breach of the Code should be addressed to the Ethics & Business Integrity Committee c/o SAPI. See **Appendix A** for the summary of the procedures.

**15.3.2** A single complaint may cover more than one (1) case, i.e. the complaint may refer to several advertisements from different Member Companies and/or for different products. Each case is handled separately by the EBIC under the main complaint reference.

Complainant's processing fee of S\$1,500 (Singapore Dollars One Thousand Five Hundred Only) is deposited payable to SAPI upon submission of complaint.

- 15.3.3** The EBIC shall table the complaint at a meeting ("**Intercompany Complaint Case Meeting**") within 6 weeks of receipt of the complaint from the Secretariat to decide if there is a case for the subject Member Company to address. Whenever necessary, the Member Company against whom the complaint is lodged shall be requested by the EBIC to give rebuttal to the allegations.
- 15.3.4** If, after due consideration, the EBIC concludes that there has been a breach of the Code, the offender shall be asked to give an undertaking in writing to stop the activity which is in breach of the Code with immediate effect and not to commit a similar offence in future. The respective Member Company should respond to the decision of the EBIC within 14 working days starting from the receipt of EBIC decision. The processing fee of S\$1,500 will be refunded to the complainant within 14 working days and the offending Member Company will pay to SAPI the S\$1,500 processing fee instead. If the EBIC concludes there has not been a breach of the Code, then the complainant's processing fee will be forfeited. The EBIC may impose an administration fee of up to S\$10,000 over and above the processing fee of S\$1,500 on Member Companies found guilty of infringements of the Code. The additional administration fee levied will be pegged to the severity of the infringement and the time and resources required deliberating on the case,
- 15.3.5** The offending Member Company can appeal the EBIC decision within 14 working days and submit the appeal in writing together with a processing fee of S\$5,000. The EBIC will convene an Appeal Committee ("**AC**") within 6 weeks of the receipt of the letter. Please refer to **Article 15.4** for the make-up of the AC. The AC decision will take effect after the approval and endorsement by Board of Directors. The affected parties will comply immediately. If the AC upholds the EBIC decision, then the processing fee of S\$1,500 will be refunded to complainant within 14 working days and the appellant's processing fee of S\$5,000 will be forfeited. If the AC overturns the EBIC decision, then the appellant's processing fee of S\$5,000 will be refunded within 14 working days and the complainant's processing fee will be forfeited.
- 15.3.6** The complainant can appeal the EBIC decision within 14 working days of the receipt of the decision and submit the appeal in writing together with the additional fee of S\$3,500 for a total processing fee of S\$5,000. The EBIC will convene an AC within 6 weeks of the receipt of the letter.
- Please refer to **Article 15.4** for the make-up of the AC.
- 15.3.7** The AC decision will take effect after the approval and endorsement by Board of Directors. The affected parties will comply immediately. If the AC upholds the EBIC decision, then the appellant's processing fee of S\$5,000 will be forfeited. If the AC overturns the EBIC decision, then the appellant's processing fee of S\$5,000 will be refunded within 14 working days and the offending Member Company will pay to SAPI the S\$1,500 processing fee instead.
- 15.3.8** In the event of the Member Company being unwilling to comply with the decision of EBIC and/or AC, and/or that the breach of the Code is perpetuated, the Ethics & Business Integrity Committee shall report its finding to the Board of Directors who may then decide whether to refer the matter to the Member Company's parent company or Head Office or publish the matter in the EBIC's Quarterly Report.

## **15.4 Appeal Committee**

- 15.4.1** The AC shall consist of a Chairman, 4 committee members and 2 members of the expert group and a secretariat staff. Please see **Appendix B** for the summary.
- 15.4.2** The Chairman nominated by the Board of Directors (“**BOD**”) of SAPI must be a member of the Board of Directors of SAPI.
- 15.4.3** The 4 committee members must be made up of the Chairman of EBIC, one member nominated by the offending Member Company, one member nominated by the appealing Member Company and one member nominated by the BOD of SAPI. If the Chairman of the EBIC is a party in the complaint, then the Chairman of the AC will appoint one of the EBIC members to replace the Chairman of the EBIC. The nominees must be either medical doctors or pharmacists who are working with any member of SAPI, excluding the affected members involved in the dispute (see **Appendix B**).
- 15.4.4** The 2 members of the expert group shall consist of any member from either the Singapore Medical Association or Pharmaceutical Society of Singapore.
- 15.4.5** The secretariat staff is the Executive Director of SAPI.
- 15.4.6** All AC members will have voting rights except the secretariat staff.

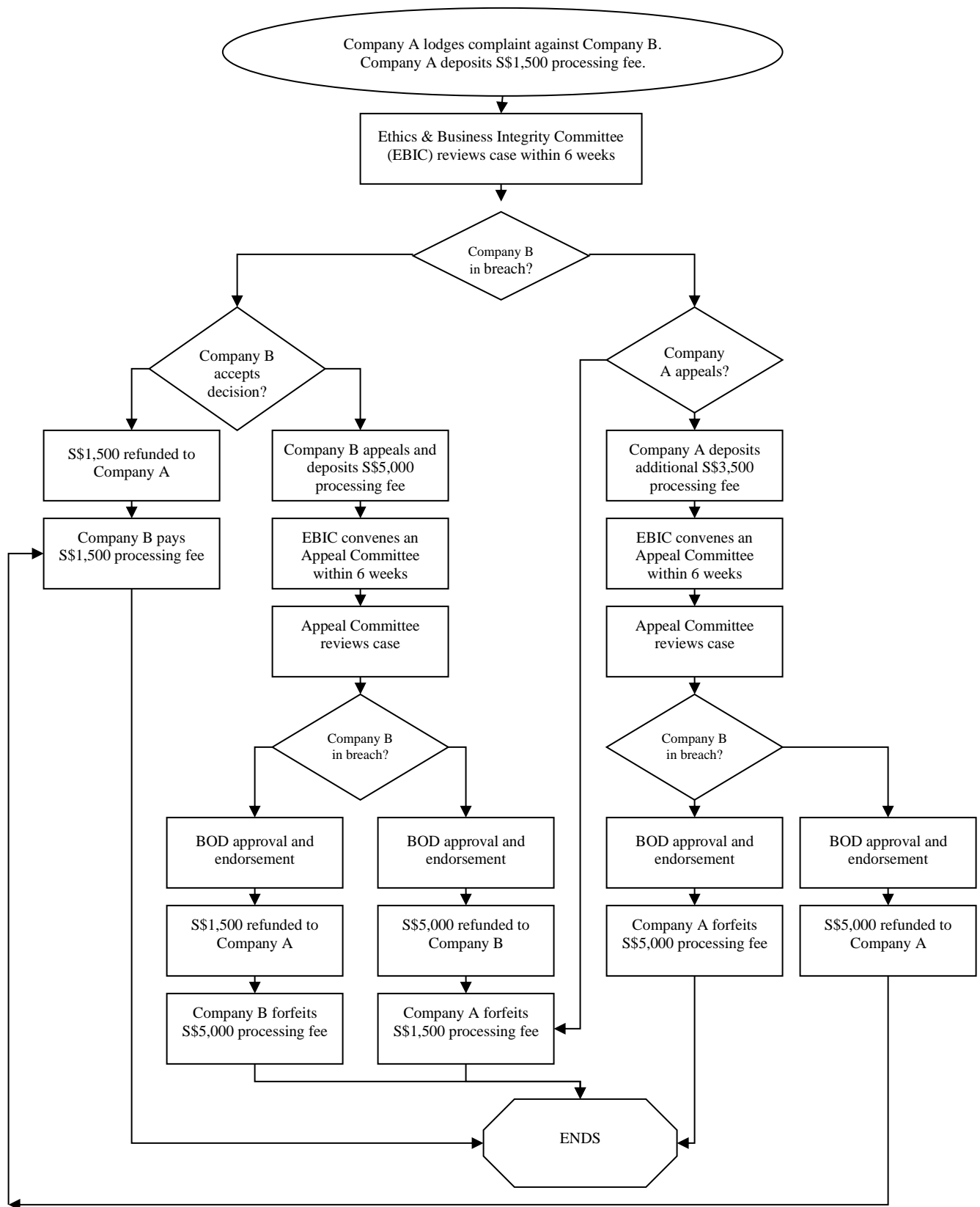
## **15.5 Sanctions**

- 15.5.1** In addition to **Articles 15.3.3 to 15.3.7**, the BOD may apply the following sanctions;
- i. In the case of international Member Companies, the matter will be referred to the Head Office of the Member Company, informing it of the case and the Board of Director's decision and appealing to the Head Office to persuade their subsidiary to comply, by withdrawing the offending material, or discontinuing the practice not later than 4 weeks from the date of the communication.
  - ii. In the interim, the BOD can invoke Paragraph 16 (b) of the SAPI constitution (the “**Constitution**”) to suspend the Member Company up to the date of an Extraordinary General Meeting being convened under Paragraph 9 (e) of the Constitution.
  - iii. If no indication of the withdrawal of the material or discontinuance of the practice is received by the set deadline, then the Board of Directors will inform the IFPMA of the matter and take action under Paragraphs 9 (d) and 16 (b) of the Constitution for the termination of the subject Member Company from the Association.
  - iv. In the case of other Member Companies, the BOD can invoke Paragraph 16 (b) of the Constitution to suspend the Member Company for a period up to the date of an Extraordinary General Meeting being convened under Paragraph 9(e) of the Constitution and take action under Paragraphs 9 (d) and 16 (b) of the Constitution for the termination of the subject Member Company from the Association.
- 15.5.2** The decision of the Board of Directors in the matter shall be final and information on above sanctions may be made known to the Health Sciences Authority, as well as Script, Market Letter and any other relevant publication, and included in the regular reports of the Ethics & Business Integrity Committee and the Annual Report of the Board of Directors to members.
- 15.5.3** Any details of complaints on alleged breaches of the Code, the decisions of the Ethics & Business Integrity Committee and the AC and subsequent actions taken by all parties in the matter may not be used by the complainant or the subject Member Company for any publicity or promotional purposes.

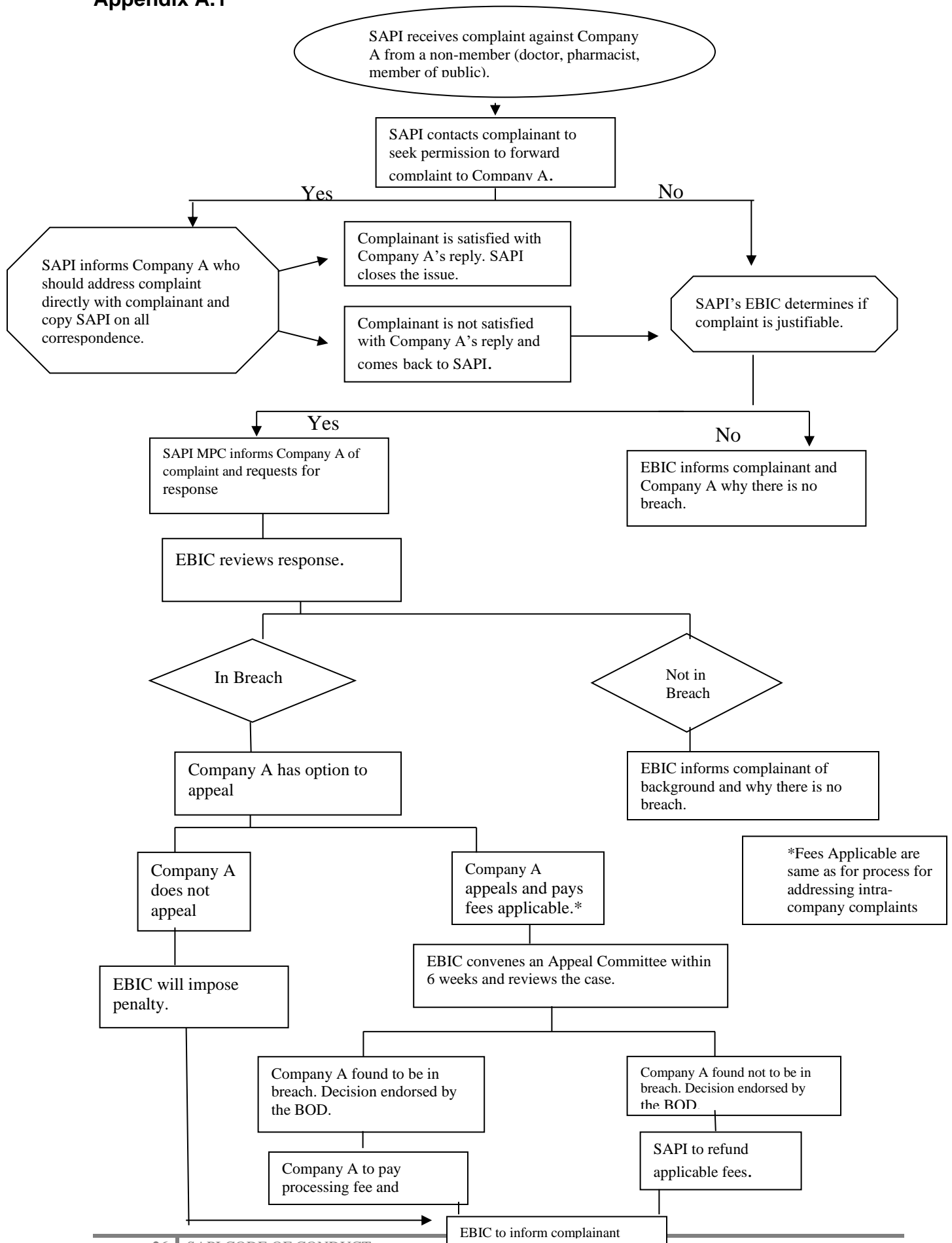


- 15.5.4** The Ethics & Business Integrity Committee, the AC, the Board of Directors, SAPI and its staff, including individuals serving in any capacity in these committees, shall not be subject to any legal action by any party on decisions taken relating to the complaint.

## Appendix A



## Appendix A.1



## Appendix B

APPEAL COMMITTEE		
Position	Membership	Number
Chairman	Director of SAPI Board of Directors	1
Committee members	Chairman of Ethics & Business Integrity Committee or Appointed EBIC member	1
Committee members	Medical doctors or pharmacists from Member Companies nominated by the parties involved in the disputes	2
Committee members	Medical doctor or pharmacist from Member Companies nominated by the SAPI Board of Directors	1
Expert group	Members of SMA and/or PSS	2
Secretariat staff	Executive Director of SAPI	1

## **Frequently Asked Questions (FAQs)**

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

### **1. Communications with the Public**

**Q: Does the Code regulate communications with the public?**

A: No. The Code covers interactions with the HCPs and the Promotion of Pharmaceutical Products. Where direct promotion to the public is allowed, this is covered by local laws and regulations. Member Companies should of course, comply with these local laws and regulations.

\*\*

### **2. Generic Products**

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

A: Yes. The definition of Pharmaceutical Products covers all prescription products, irrespective of whether they are branded or covered by a patent or other intellectual property protection. It must be recognised, however, that some generic manufacturers may not be Member Companies. Their activities therefore fall outside the reach of the Code.

\*\*

### **3. OTC and Health Supplement Products**

**Q: Under Article 1, products for infant nutrition, diagnostic tests and surgical and medical devices and OTC Products directed to consumers are not included within the scope of the Code. Does the Code apply to the promotion and marketing of the above mentioned range of products that may also be prescribed by the HCPs?**

A: No. The Code only applies to the promotion of Pharmaceutical Products intended to be used on the prescription of, or under the supervision of a HCP. Even though products such as infant nutrition, diagnostic tests and surgical and medical devices and OTC Products directed to consumers are not covered in the scope of the Code, Member Companies that have these dual “pharmaceutical” and “non-pharmaceutical” offerings are encouraged to adhere to the general principles of the Code.

\*\*

### **4. Pricing and Terms of Trade**

**Q: Does the Code prohibit Member Companies from giving its customers discounts or other favorable trade terms for the supply of Pharmaceutical Products?**

A: No. The Code does not restrain or regulate commercial trade terms for the supply of Pharmaceutical Products.

\*\*

**Q: Does the Code apply to the promotion and marketing of Pharmaceutical Products to commercial customers who are also practising HCPs, such as a pharmacist who operates his/her own practice?**

A: The Code does apply to the promotion and marketing of Pharmaceutical Products to such a customer. However, the Code does not restrain or regulate commercial trade terms for the supply of Pharmaceutical Products to customers. In any dealings with such a customer, Member Companies should respect the customer's role as a HCP and, if applicable, comply with the requirements of the Code.

\*\*

**Q: Does the Code apply to the promotion and marketing of Pharmaceutical Products to commercial customers who are not HCPs? What if the customer is a HCP by qualification but is not practising?**

A: No. The Code only applies to interactions with practising HCPs. Promotion and marketing to commercial customers (whether or not they are HCPs) may of course be governed by other laws and regulations, such as those that restrict or prohibit inaccurate, misleading or deceptive advertising and promotion or restrict or prohibit the giving of inducements to public officials or employees.

\*\*

**Q: Does the Code cover price lists or other documents describing terms of trade?**

A: No.

\*\*

**Q: Could a false price claim or a misleading price comparison in promotional material be processed under the Code?**

A: Yes, this is possible when a Member Company is inappropriately using pricing information in its promotional materials or activities.

\*\*

## **5. Consultancy Agreements**

**Q: In the absence of any formal industry guidelines or local laws, how should Member Companies interact with HCPs who are offering legitimate consultancy services?**

A:

- i. It is appropriate for consultants who provide services to be offered reasonable fair market value compensation for those services and to be offered reimbursement for reasonable travel, lodging, and meal expenses incurred as part of providing those services. Compensation and reimbursement that would be inappropriate in other contexts can be acceptable for genuine consulting arrangements. Token consulting or advisory arrangements should not be used to justify compensating HCPs. The following factors support the existence of a genuine consulting arrangement (not all factors may be relevant

to any particular arrangement): a written contract which specifies the nature of the services to be provided and the basis for payment of those services;

- ii. a legitimate need for the services has been clearly identified in advance of requesting the services and entering into arrangements with the prospective consultants;
- iii. the criteria for selecting consultants are directly related to the identified purpose and the persons responsible for selecting the consultants have the expertise necessary to evaluate whether the particular HCPs meet those criteria;
- iv. the number of HCPs retained is not greater than the number reasonably necessary to achieve the identified purpose;
- v. the retaining Member Company maintains records concerning and makes appropriate use of the services provided by consultants; and
- vi. the hiring of the HCP to provide the relevant service is not an inducement to prescribe a particular product.

\*\*

## **6. Non-Promotional Information**

**Q: What are the examples of non-promotional information that are not covered by the Code?**

A: An example of non-promotional information that is not covered by the Code would be correspondence which addresses a specific question about a particular medicinal product and which is accompanied by material of a non-promotional nature.

Non-promotional, general information about Member Companies (such as information directed to investors or to current/prospective employees) are not covered by the Code. Examples include financial data, descriptions of research and development programs, and discussion of regulatory developments affecting the Member Company and its products.

\*\*

## **7. Disguised Promotion**

**Q: Is it ever appropriate for a Member Company to publish promotional materials that appear to be independent editorial content?**

A: No. Where a Member Company's finances or otherwise secures or arranges the publication of promotional material in journals, such promotional material must not resemble independent editorial matter.

\*\*

**Q: How does the prohibition of pre-approval promotion affect compassionate use programmes?**

A: The Code does not prohibit compassionate use programmes, which must of course comply with all applicable laws, regulations and codes. Care should be taken to ensure that communications for a compassionate use programme are not, in effect, advertisements for an unlicensed medicine or use.

## **8. Use of Comparisons**

**Q: Does the Code allow for comparisons between different products to be included in promotional materials?**

A: Yes. Any comparison made between different Pharmaceutical Products should be based on relevant and comparable aspects of the products and be capable of substantiation. Comparative advertising should not be misleading.

\*\*

## **9. Use of Quotations**

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

A: Yes. Quotations from medical and scientific literature or from personal communications should be faithfully reproduced (except where adaptation or modification is required in order to comply with any applicable codes, in which case it must be clearly stated that the quotation has been adapted and/or modified) and the precise sources identified. Quotations should not change or distort the intended meaning of the author or clinical investigator or the significance of the underlying work or study.

\*\*

## **10. Reprints**

**Q: Are reprints considered as promotional material under the Code?**

A:

- i. Reprints of scientific and medical articles as such are not developed by Member Companies and hence should be considered as non-promotional in a standalone context.
- ii. However, if reprints are acquired by a Member Company for unsolicited distribution (with or without other companies' originated documents) to HCP, they would be considered as promotional materials.
- iii. In the above scenario, the materials provided (including the reprints) should include data that is within the approved label issued by the Health Sciences Authority for the product in the country.
- iv. Reprints outside of current labelling should be provided to HCPs only if there is an unsolicited request for information from the HCP
- v. Reprints that include off-label information and are provided strictly based on unsolicited requests, should be provided only via the organisation's medical team and with clear disclaimers provided by the medical team to that context (which can be via a cover letter, email or verbally to the HCP).

\*\*

## **11. Events Involving Foreign Travel**

**Q: When is it appropriate and justified for a Member Company to organise or sponsor a Company Standalone Event for HCPs outside of their home country?**

A: Member Companies must not organise or sponsor any Company Standalone Event for HCPs that take place outside of Singapore, whereby the majority (i.e. fifty-one percent (51%) or more) of the attendees considers Singapore as their home country. However, Member Companies may pay or



reimburse reasonable out of country travel and accommodation expenses that comply with **Article 7.2.7.2.3vi** only when it fulfils requirements in connection with **Article 7.4**.

\*\*

**Q: What is considered as the home country of a HCP?**

A: Under the Code, the home country of a HCP is the country in which he/she practices.

\*\*

**Q: Is Article 7.1.2 applicable to invitations and Events organised directly by a counterpart from an overseas company affiliate, which is not a Member Company or SAPI affiliate?**

A: Although the Code is silent on this, we should follow is the code of the home country of the HCP. SAPI's affiliates are responsible in communicating the home country's code to any overseas counterparts when they invite local doctors.

\*\*

**Q: What if an invited overseas speaker does a 'stop over' lecture in Singapore, and is say, coming from Hong Kong (less than 6 hours travel), but originally departed from the United Kingdom. Is it OK to fly business class?**

A: Yes, if the speaker resides in a city that is more than 6 hours flight time from Singapore and the primary purpose of the trip is for a speaker tour.

\*\*

**Q: If a HCP is invited as a speaker from Singapore to Manila or any Asian countries within 6 hours travel, can the HCP travel business class if the inviting country's regulation states that economy class tickets are provided for air travel of less than 4 hours?**

A: No. The Code will apply for all Singapore-based HCPs.

\*\*

## **12. Entertainment**

**Q: The Code prohibits stand-alone entertainment, leisure or social activities to HCP and other stakeholders. Are there any exceptions to this rule and how should Member Companies interpret this in local practice?**

A: When a Member Company organises an Event, refreshments and/or meals which are incidental to the main purpose of the Event can be provided if they are provided exclusively to participants of the Event and are moderate and reasonable as judged by local standards. However, it would not be appropriate for any Member Company to fund attendance at a concert, purchase entertainment tickets or pay for entertainment in any form as this would be stand-alone entertainment. Such entertainment or recreational benefit should not be offered, regardless of (1) the value of the item; (2) whether the Member Company engages the HCP as speaker or consultant; (3) whether the entertainment or recreation is secondary to an Event.

However, if there is background music or a local performance at the venue where the Event is taking place, which is not paid for by the Member Company, this may be permitted. As an example, an appearance by a well-known TV or pop star would not be acceptable, whereas a folk dance display or performance by a local singer would be acceptable as entertainment for a meal interlude and not considered as a means of attracting HCPs to an Event.

\*\*

**Q: Under Article 7.2, it is mentioned that “limited” hospitality of modest nature and secondary to the main purpose of the Event is acceptable. Please clarify if sight-seeing tours are allowed if it constitutes less than twenty five percent (25%) of the duration of the sponsored Events?**

A: The primary purpose of the sponsored Events is for scientific and educational purposes. Sponsoring, providing and/or organising of any sight-seeing tour is not allowed under the twenty five percent (25%) time allocated for hospitality activities during the sponsored Events.

\*\*

### **13. Promotional Aids & Literature**

**Q: Can promotional aids or gimmicks be distributed at an exhibition booth?**

A: No.

\*\*

**Q: What are the expectations of a Member Company when promotional materials have expired?**

A: It is the responsibility of the Member Company to ensure that out of date materials are no longer distributed and destroyed. Date of first use of all promotional materials circulated to the market shall not be more than two (2) years from the date of approval. Any materials used beyond this point must be re-approved. Henceforth, all published promotional material shall be dated and updated regularly. Thus, date of print must be defined on the document. Please refer to your own company policy, if applicable.

\*\*

**Q: Is it necessary for prescribing information to be attached to all promotional material?**

A: This depends on whether the promotional material is a full advertisement or a reminder advertisement as defined under **Articles 5.13** and **5.14**.

Full advertisements are those, which include promotional claims for the use of the products. Full advertisements must include prescribing information as stated under **Article 5.13**.

\*\*

### **14. Items of Medical Utility**

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

A: Item of medical utility should be items that:

- i. have a value of less than S\$200 per item;

- ii. do not offset/subsidise routine business expenses that a HCP might otherwise incur;
- iii. are not offered on more than an occasional basis (i.e. not more than 2 occasions per HCP per year);
- iv. beneficial to enhancing the provision of medical services and patient care; and
- v. do not have value to HCPs outside the scope of their practice and educational need.

Examples of items of medical utility might include an anatomical model for use in an examination room. However, examples of items which would not be permissible as items of medical utility include a VCR, CD, DVD player, stethoscope, sphygmomanometer or refrigerator.

\*\*

**Q: In what circumstances may items of medical utility be considered as “offsetting routine business expenses” of a HCP?**

A: A HCP’s practice generates certain routine costs, such as rent, administrative costs or items that are needed in order to conduct patient consultation. As a general principle, Member Companies should not provide such items to HCPs. Consequently, the Code allows Member Companies to provide certain inexpensive items of medical utility (e.g. anatomical model for use in an examination room, etc.) to HCPs only to the extent that they do not offset costs that would otherwise be routinely incurred by a HCP. As for example, a HCP will anyway need a Stethoscope or BP Machine or a Weighing machine as part of the clinical practice and hence offering such item would be considered paying for the routine cost of HCPs.

\*\*

**Q: Under Article 7.5.3, should there be a limit to number of items of medical utility for individual HCP?**

A: Items should not be offered on more than an occasional basis, even if each individual item is appropriate. Although it is not specified, guidance is not more than 2 occasions per HCP per year.

\*\*

**Q: Is it acceptable to print the Member Company’s logo on any medical books/journals or items of medical utility?**

A: It is acceptable to print/put the Member Company’s logo on medical books/journals or items of medical utility. However, brand names are not allowed unless the product’s name is essential for the correct use of the item by the patient.

\*\*

## 15 Gifts, Donations and Grants

**Q: Under Article 7.5.2, we see a ban on the “congratulatory flowers”. Is it acceptable to send “congratulatory items” to HCPs?**

A: Article 7.5.2 puts a ban on all kind of promotional and cultural aids or gifts. This is consistent with the updated code of IFPMA. So, congratulatory flowers for any reason or other cultural items are now strictly prohibited under the SAPI Code.

\*\*

**Q: Is it acceptable to send flowers to a HCP bereaving the loss of a loved one?**

A: No, The Code strictly prohibits giving flowers to HCPs whatever be the occasion. Please refer to **Article 7.5.2** for detail.

\*\*

**Q: Is a thumb drive considered a personal gift or something which is relevant to the practice of medicine?**

A: Giving a thumb drive to HCPs as a promotional aid or without any appropriate reason is strictly prohibited under the Code. However, if the thumb drive is required to pass educational content or information data to the HCPs and the storage capacity of the thumb drive is commensurate with the content, then it may be appropriate to offer it to HCPs.

\*\*

**Q: Can Member Companies pay for a bottle of congratulatory bottle of champagne for their customer's Clinic Opening?**

A: No. Under **Article 7.5.2**, Member Companies are not allowed to give any cultural courtesy gift to HCPs or clinics.

\*\*

**Q: Can I provide an iPad as an educational item to a doctor if I download educational materials onto it?**

A: No. Under our Code, the item must serve a genuine educational function, have medical utility or benefit patients. An iPad or other similar electronic devices such as smartphones and tablets, even if downloaded with educational materials, are not permissible as this would be a substantial personal benefit to a HCP, and would not be justifiable to communicate the educational content of the material.

\*\*

**Q: As a business norm in Singapore, Member Companies are frequently invited by Institutions/Groups/Private Hospitals to sponsor their sports day, staff social events and Dinner & Dance. Is this allowed?**

A: Under **Article 7.1.6**, "*No stand-alone entertainment or other leisure or social activities should be provided or paid for by Member Companies*". Member Companies' relationship with HCPs must be for the purpose of advancing medical and patient care. Social activities or events such as dinners and dance are not educational or scientific events and are therefore deemed inappropriate for Member Companies to support.

\*\*

**Q: The above Institutions/Groups/Private Hospitals event may also happen for fund raising (intended for needy patients) or scientific annual meeting with educational intent. Are member companies allowed to sponsor such events?**

A: Yes. If the events are intended for educational purpose or advancing healthcare, it may be appropriate to support if the member company's policy and Code support it.

**Q: Can member companies provide grants towards financial support for HCPs to attend Third Party Educational Events?**

A: Member companies may provide financial support in the form of grants, to sponsor HCPs to attend Third Party Educational Events, provided such financial support is offered in accordance to guidance provided in Articles 7.2.1 - 7.2.4.

\*\*

**Q. Under Article 7.5.4 Donations, can member companies initiate donations for charitable purposes to charitable organisations/institution?**

A Yes. Member companies can initiate monetary, used items or product donations for charitable purposes to charitable organizations/institutions in accordance to Article 7.5.4.

\*\*

## **16 Events Sponsorship**

**Q: How should a Member Company handle a case where the sponsor agrees to the sponsorship of an international/regional Event even before a venue is selected, and later finds out that it will be held at an Integrated Resort ("IR")?**

A: It is best not to make any commitment prior to confirmation of venue.

\*\*

**Q: Please elaborate on the term "venues that are renowned for their leisure and entertainment facilities" under Article 7.1.4.**

A: A general guide is to consider what the primary purpose of the business entity is. If the entity makes its bulk of profits from leisure or entertainment, then such venues are not appropriate.

\*\*

**Q: What is considered an extravagant venue? Are restrictions on extravagant venues applicable to overseas Events?**

A: A suitable guide is to consider whether the majority of people (from Member Companies or otherwise) would consider a venue to be extravagant. The Code applies to Events being conducted in Singapore. For overseas Events, the relevant country's code will apply.

\*\*

**Q: Under what circumstances can Member Companies sponsor or hold Events at leisure and entertainment venues? More specifically, can Member Companies sponsor the registration fee of HCPs to congresses organised by a third party, where the congress is held at a venue with a casino area?**

**A:** Such sponsorship is not appropriate. Registration is a form of sponsorship and it is therefore covered under **Article 7.1.4**.

**\*\***

## **17 Others**

**Q: Can the Plaintiff and Defendant be represented at the Intercompany Complain Case Meeting?**

**A:** The Plaintiff and Defendant will be called for representation during the Intercompany Complain Case Meeting. No external legal counsel is allowed.

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