

(Front Cover)



**CODE OF PRACTICE**

**21<sup>st</sup> EDITION**  
**7<sup>th</sup> October 2022**

**THE HONG KONG ASSOCIATION  
OF THE PHARMACEUTICAL INDUSTRY**

(Inside Front Cover)

## Mission Statement

*To drive the expedient access to  
innovative healthcare solutions for the people of  
Hong Kong and Macao with high ethical standard.*

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# HKAPI CODE OF PRACTICE

## 21<sup>st</sup> edition, 2022

### **PREAMBLE**

The Hong Kong Association of the Pharmaceutical Industry (“HKAPI”) was formed in 1968 with a mission to drive the expedient access to innovative healthcare solutions for the people of Hong Kong and Macau with high ethical standards.

First drafted in 1971, the HKAPI Code of Practice (the “Code”) has been systematically updated in order to be responsive to the expectations of society. The Code and its supplementary guidelines, in accordance with internationally defined standards of good practice, are intended to serve as a basis for our member companies to make ethical decisions in their conduct of professional work and interactions with healthcare professionals (HCPs) and other stakeholders like medical societies and patient organizations. It also serves as a basis for judging formal complaints with respect to our professional ethical standards.

Member companies should abide by the Code not just in terms of words, but also in spirit grounded in integrity, values and principles in line with ever-changing societal expectations. Interactions with healthcare professionals, medical societies, patient organizations and/or other stakeholders are designed to benefit patients and enhance the practice of medicine. Members should not only strive to meet the basic standards, but also exceed them whenever possible, to build, sustain and grow that trust with patients. Trust is the basis of reputation and essential for innovation,

All member companies – be they full members, affiliate members or associate members – of the HKAPI, are obliged to observe the Code in order to achieve and maintain high professional and ethical standards across the industry, as we are committed to the improvement of the health of humankind through production, research, development and distribution of pharmaceutical products.

The Code is applicable to all our member companies. We also strongly encourage non-member pharmaceutical companies to comply with the Code and to uphold the industry standard to a higher ethical standard and to build trust with patients and society. References to members and/or member companies in the provisions of the Code may be taken to extend to apply to the standard expected from non-member pharmaceutical companies insofar as applicable (except Section 14 Complaint Procedure).

### **INTRODUCTION**

- I. We, the members of the HKAPI, including full members, affiliate members and associate members, are committed to the improvement of the health of humankind through research, development, production and distribution of pharmaceutical products of reliable quality, in accordance with internationally defined standards of good practice and are aware of our responsibilities in providing accurate information on our products.
- II. We accept the principles:
  - (a) That, as part of its commitment to health, the industry has an obligation and responsibility to provide accurate information and education about its products in order to establish a clear understanding of the appropriate use of pharmaceutical products, and
  - (b) That the Code should be consistent with high ethical standards and that information should be designed to help improve services to patients. Information should be

provided with objectivity, truthfulness, fairness, balance and in good taste and should conform to all relevant laws and regulations of the Hong Kong and Macau Special Administrative Regions (hereafter referred to as “Hong Kong” and “Macau” respectively, and each as a “City” herein). Claims for therapeutic indications and conditions of use should be based on valid scientific evidence and include clear statements with respect to side effects, contraindications, and precautions.

- III. Accordingly, to ensure that these responsibilities and principles are fulfilled, we adopt the Code for our activities in Hong Kong and Macau, which indicates acceptance of, and embodies the principles set out in the 2019 IFPMA Code of Practice (“IFPMA Code”), including the provision that we shall require our licensees and agents, if any, to observe the Code and the IFPMA Code.

## **1. GENERAL PRINCIPLES**

- 1.1 Member companies’ relationships and interactions with healthcare professionals and other stakeholders are intended to benefit patients and to enhance the practice of medicine and should never bring discredit upon the pharmaceutical industry.
- 1.2 No financial benefit or benefit-in-kind may be provided or offered to a HCP or any stakeholders in exchange for prescribing, recommending, purchasing, supplying or administering products or for a commitment to continue to do so. Nothing may be offered or provided in a manner or on conditions that would have an inappropriate influence on a HCP’s prescribing practices.

Inappropriate financial, material or personal benefits (such as theatre, concerts, sporting events, festive gifts), including inappropriate or lavish hospitality, should not be offered to HCPs or any stakeholders either directly or indirectly, whether through clinics, healthcare organizations, medical societies or patient organizations.

Gratuitous payments in cash or cash equivalents (such as gift certificates, free flight upgrades) or personal services must not be offered to HCPs or any stakeholders under any circumstances. For the purpose of this Section, personal services refer to any type of service unrelated to the HCP’s profession or the stakeholders’ mission which may confer a personal benefit to the HCP or the stakeholders.

- 1.3 In all cases, all relevant laws, local regulations and industry codes must be observed and companies have a responsibility to check local requirements, in advance of preparing promotional or non-promotional material or events in any specific city.
- 1.4 The principle of transparency should be observed. It should be clearly indicated by whom it has been sponsored, whether member companies are conducting promotional or non-promotional activities.
- 1.5 Promotion should not be disguised. Clinical assessments, post-marketing surveillance and experience programs and post-authorization studies must not be disguised promotion. Such clinical assessments, post-marketing surveillance, experience programmes and post-authorization studies must be conducted with a primarily scientific or educational purpose. Material relating to pharmaceutical products and their uses, whether promotional in nature or not, which is sponsored by a company should clearly indicate the sponsor.

- 1.6 Substantiated information on serious and unexpected adverse reactions associated with pharmaceutical products should be reported to the appropriate health authority as a priority.
- 1.7 In all matters of application, interpretation and enforcement of any section of the Code, it is to be understood that compliance with local laws, regulations and regulatory decisions and requirements will take precedence.
- 1.8 Other than pharmaceutical products as provided hereunder, the spirits and principles of the Code shall apply to the dealings of medical devices and nutritional productions by member companies to the extent possible.

## **2 DEFINITION OF CERTAIN TERMS FOR PURPOSE OF THE CODE**

- 2.1 The term “promotion” means any activity undertaken, organized or sponsored by a member company to promote the prescription, recommendation, supply, administration or consumption of its pharmaceutical product(s) through all methods of communications, including the internet.

The term “promotional material” means printed or digital promotional material, which includes information such as the name of the product, active ingredients, name of the member company, date of production and other specific product information such as product claims, features, and/or benefits. For additional details, please refer to Section 4 of the Code.

The term “promotional item”, including promotional aids and promotional gimmicks, means a non-monetary item given for a promotional purpose (which does not include promotional materials). For details on use of promotional items, please refer to Section 6.2 of the Code.

The term “non-promotional activities” means activities that are intended primarily for educational or informational purposes. Examples of such are public disease awareness campaigns, scientific advisory board meetings, dissemination of non-promotional information and unbranded educational activities.

The term “non-promotional information” refers to any medical and/or scientific information and/or materials primarily for educational or informational purposes. For details, please refer to Section 6 of the Code.

- 2.2 The term “pharmaceutical product” means any pharmaceutical product or substance intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans, or affects the structure or any function of the human body, which is promoted and advertised to HCPs rather than directly to the lay public. It is anticipated that members will adhere to the spirit of this Code when promoting any of their pharmaceutical products, including those that may legally be sold over-the-counter.
- 2.3 The term “healthcare professional (HCP)” should be interpreted to extend to medical, dental, pharmacy, nursing and/or other para-medical professionals, including students or trainees in all such related disciplines, who in the course of his or her professional activities may prescribe, recommend, purchase, supply, sell or administer a pharmaceutical product.
- 2.4 The term “healthcare organization” means any private or public sector organization, institution or association that is comprised of HCPs and/or that provides healthcare services.

- 2.5 The term “medical representative,” as it applies in the context of this Code, means anyone representing a member company to have interactions with healthcare professionals.
- 2.6 The term “prescribing information” means comprehensive product information as submitted to and filed with the relevant division of the Department of Health in connection with the registration of a pharmaceutical product and any subsequent amendments.
- 2.7 The term “patient organization” means typically a not-for-profit institution that primarily represents the interests and needs of patients, their families and/or caregivers.

**3. GENERAL PROVISIONS RELATING TO PROMOTIONAL OR NON-PROMOTIONAL ACTIVITIES**

- 3.1 Where local laws and regulations are in force, which define relevant requirements, those shall take precedence.
- 3.2 Information in promotional or non-promotional materials should be based on an up-to-date evaluation of evidence that is scientifically valid and should not give an incorrect or misleading impression.
- 3.3 All information should be accurate, objective, fair and balanced and should not be misleading either directly or by implication.

Any claim used in promotional material should be documented either by the prescribing information authorised by the City authorities or by other accessible sources. In the latter case, the original source should be indicated as reference.

Superlatives should not be used in product claims unless these can be scientifically substantiated.

The use of a competitor product brand name requires written consent from that company.

Absolute or all-embracing claims should be used with caution and only with adequate qualification and substantiation. For example, the word “safe” or “no side effects” must not be used without qualification.

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

Interactions with HCPs should be focused on informing HCPs about products, providing scientific and educational information and supporting medical research and education.

Particular care should be taken that essential information related to pharmaceutical products’ safety, contraindications, side effects or potential hazards is appropriately and consistently communicated subject to the legal, regulatory and medical practices of the City.

- 3.4 Disparaging references to other products or manufacturers should be avoided.
- 3.5 Comparative claims should be based on data from adequate and well-controlled clinical studies and should be consistent with other clinical data.

- (a) Non-clinical comparative studies on antibiotics are acceptable provided the tests adhere to well-established scientific and evidence based standards used in the medical community.
  - (b) Statements based on animal models or in-vitro data must be identified clearly.
  - (c) The claimed differences between pharmaceutical products should be statistically significant.
  - (d) Comparative statements should mention the pharmaceutical product under comparison.
- 3.6
- (a) Member companies should establish and maintain appropriate procedures to ensure full compliance with relevant codes and applicable laws in the review and monitoring of all their promotional activities and materials.
  - (b) Member companies should ensure that relevant employees receive training appropriate to their role.
  - (c) Promotional communications, whether in Chinese or English, should have medical clearance by the responsible person before their release. The responsible person must have appropriate scientific or healthcare qualifications.
- 3.7
- When package inserts are printed in Chinese and English, the information imparted in both languages should be the same.
- 3.8
- No pharmaceutical product shall be promoted in the City until the requisite approval for marketing has been given in the City. However, this provision is not intended to abridge 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 pharmaceutical products, including appropriate dissemination of investigational findings in scientific or lay communications media and at scientific conferences. Nor should it restrict public disclosure to stockholders and others concerning any pharmaceutical product as required or desirable under law, rule or regulation.
- 3.9
- Promotion should be capable of substantiation either by reference to the approved labelling or by scientific evidence. Such evidence, including data on file, should be made available on request in a reasonable amount of time. Member companies should deal objectively with requests for information made in good faith and should provide data, which is appropriate to the source of the inquiry.
- 3.10
- A public disease awareness campaign targeted at the public must not promote pharmaceutical products.

#### **4. PRINTED AND DIGITAL PROMOTIONAL MATERIALS TO HEALTHCARE PROFESSIONALS**

- 4.1 All promotional materials, whether in printed or digital form (including audiovisuals), excluding reminder promotions (refer to Section 4.5), issued for promotional purposes by member companies or with member companies' authority should include the following:
- (a) The name of the product (normally the brand name);



- (b) The name, address and telephone number of the manufacturer or the manufacturer's authorised agent, or the business name and address of the part of the manufacturer's business responsible for the sale of the product.
  - (c) The active ingredient(s), using approved names where such exist, or other non-proprietary names; alternatively, the non-proprietary name of the product if it is the subject of an accepted monograph. The generic name should be in close proximity to the trade name.
  - (d) Abbreviated prescribing information which should include an approved indication or indications for use together with the dosage and method of use; and a succinct statement of the contraindications, precautions, and side effects.
  - (e) Information provided in (a) to (d) must be up-to-date and valid according to the respective registration details in the applicable City.
- 4.2 Promotional material should conform, both in text and illustration, to canons of good taste and should recognise the professional standing of the recipients.
- 4.3 All promotional materials must include the date of approval (i.e. the year and the month).
- 4.4 Specifically, in the case of pharmaceutical product related websites:
- (a) the identity of the pharmaceutical company and of the intended audience should be readily apparent;
  - (b) the content should be appropriate for the intended audience; and
  - (c) the presentation (content, links etc.) should be appropriate and apparent to the intended audience.
- 4.5 Reminder promotion refers to a short advertisement targeting HCPs containing no more than the brand and generic names and a simple statement of indication(s) to designate the therapeutic category of the product, the company name and contact information. Reminder promotions must not include product claims, features or benefits beyond the scope of a simple statement of indication(s).

## **5. SYMPOSIA, CONGRESSES AND OTHER MEANS OF VERBAL COMMUNICATION TO HEALTHCARE PROFESSIONALS**

Symposia, congresses and the like are indispensable for the dissemination of knowledge and experience. Scientific objectives should be the principal focus in arranging such meetings. Any hospitality offered should be reasonably related to the scientific agenda and should not be inconsistent with the Code.

Including those events organized by third parties i.e. medical societies, member companies should follow the guidelines in Section 5 when deciding whether to support it.

### 5.1 Symposia, congresses and other verbal communications means

When a member company sponsors a symposium, congress or other promotional, medical/health care or educational programme (an "Event"), other than a breakfast, lunch or dinner Event of no more than 3 hours in duration covering a clear scientific agenda, a minimum of two-thirds (2/3) of the time (calculated from the official start to the end of the Event agenda for each day)

shall be devoted to the scientific agenda, which shall be prepared and distributed to participants before the Event. In addition:

- (a) No member company may organize or sponsor an Event for HCPs (including sponsoring individuals to attend such an Event) that takes place outside of their home city unless it is appropriate and justified to do so from a logistics or security point of view. International scientific congresses and symposia that draw participants from many countries are therefore justified and permitted;
- (b) Statement of sponsorship by a member company should be clearly stated in advance of the meeting and any related proceedings. Printed, audio-visual, or digital material arising from such Events should accurately reflect the presentations and discussions;
- (c) Scientific information which appears on, or is distributed to participants from, exhibition stands or promotional booths as part of an Event must not refer to pharmaceutical products which are not registered in the country/market where the Event takes place, or which are registered under different conditions or indications. Any request for information on pharmaceutical products not registered in the country/market where the Event takes place or otherwise registered under different conditions or indications should be directed to the medical team for response;
- (d) With the exception of activities under Section 5.3(h), entertainment of any nature (including theatre, concerts or sporting events) is prohibited. Hospitality should be reasonably related to the Event, reasonable by the City's standards, and limited to travel, meals, accommodation and genuine registration fees;
- (e) Any support to an individual HCP to participate should not be conditional upon any obligation to prescribe, recommend, purchase, supply or administer any pharmaceutical product;
- (f) If the programme is accredited for postgraduate medical education by a medical or other professional organisation, responsibility for the programme content remains with the organisation responsible for obtaining accreditation for the meeting, and industry support, if any, should be disclosed.

## 5.2 Travel, Venue and Accommodation

- (a) When sponsoring HCPs to attend Events, standard economy class should be provided to professionals for one-way flight time of 5 hours or less and standard economy class should also be the prioritized consideration for one-way flight time of more than 5 hours (and not include any travel or other sponsorship for their family members or companions).
- (b) All Events should be held in an appropriate venue that is conducive to the scientific or educational objectives and the purpose of the Event. Member companies should avoid using lavish or extravagant venues. The location and venue should not be the main attraction of the event or be perceived as such.
- (c) For accommodation, member companies should avoid using lavish or extravagant hotels.

### 5.3 Sponsorship

Member companies may sponsor HCPs to attend Events provided such sponsorship is in accordance with the following requirements:

- (a) The Event complies with the hospitality requirements in the Code;
- (b) Sponsorship to HCPs is limited to the payment of travel, meals, accommodation and registration fees under Section 5.1(d). Any registration fees sponsored shall be related to the support of the scientific agenda of the Event, and not for the provision of entertainment or other leisure or social activities inconsistent with Section 5.3(h);
- (c) No payments are made to compensate HCPs for time spent in attending the Event;
- (d) Any sponsorship provided to an individual HCP must not be conditional upon an obligation to prescribe, recommend, purchase, supply or administer any pharmaceutical product.
- (e) Member companies should not pay any costs associated with individuals accompanying invited HCPs.
- (f) Hospitality should be limited to refreshments and/or meals incidental to the main purpose of the Event and should only be provided:
  - (i) to participants of the Event and not their guests; and
  - (ii) if moderate and reasonable as judged by local standards.
- (g) Member companies are encouraged to follow the guidance on the Appendix of this Code with respect to the meaning of the terms “nominal” and “reasonable” as used in Sections 5.1(d), 5.3(h) and 6.2 of the Code.
- (h) No stand-alone entertainment or other leisure or social activities should be provided or paid for by member companies at Events, except for entertainment of a modest nature according to reasonable local standards which is incidental to refreshments and/or meals.

### 5.4 Fees for Services

HCPs may be engaged as consultants and advisors for services such as speaking at and/or chairing meetings and 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. To the extent relevant to the particular arrangement, the arrangements which cover these genuine consultancies or other services must fulfil all the following criteria:

- (a) a written contract or agreement must be signed 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; all necessary authorization (including from the HCP's principal) must be obtained if applicable;
- (b) a legitimate need for the services must be clearly identified and documented in advance;

- (c) 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;
- (d) the number of consultants retained must not be greater than the number reasonably necessary to achieve the identified need;
- (e) the hiring of the consultant to provide the relevant service must not be an inducement to prescribe, recommend, purchase, supply, and/or administer any pharmaceutical product; and
- (f) the compensation for the services includes the fair market value of the services provided according to where the HCP practices, and
- (g) whenever applicable, the reimbursement of out of pocket expenses including travel and accommodation that must be reasonable by the location's standards. These should be included in the compensation arrangements and documented.

## **6. PROMOTIONAL ITEMS AND NON-PROMOTIONAL ITEMS (SUCH AS EDUCATIONAL ITEMS AND ITEMS OF MEDICAL UTILITY)**

- 6.1 Any items provided to HCPs or any other stakeholders, where permissible, must never constitute an inducement to prescribe, recommend, purchase, supply, sell or administer a pharmaceutical product.

All items must be properly designed with clear intent. Any medical, scientific or technical information included in such materials must be capable of scientific substantiation and must be accurate, truthful and not misleading.

### 6.2 Promotional Items

Promotional items of nominal value, provided free of charge and on an infrequent basis, are permissible as long as they are for the promotion of over-the-counter products and are related to the HCP's practice and/or entail a benefit to patients.

A promotional item offered or provided to HCPs in relation to prescription-only medicines is prohibited. Examples of such prohibited items include company or product branded calendars, mouse pads and sticky notes.

### 6.3 Non-Promotional Items

Non-promotional items must not be designed or used to promote any pharmaceutical products with any promotional messaging and product branding. Examples of such items include disease awareness materials.

#### (a) Informational/Educational Items

Informational and educational items provided to HCPs for patient use 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. Examples of "correct use" may include, but are not limited to, proper use of a device, proper dosing, contraindications, what not to be taken with the medication, storage conditions, potential/common side effects. Efficacy information and product comparisons are not permitted.

For those informational items for supporting patients' access and affordability of prescribed medication with specific eligibility criteria, such as patient

assistance programmes, patient support programmes and rebate programmes etc., specifying indication as it relates to the eligibility criteria may be permitted.

All these materials must comply with all local laws and regulations such as the Undesirable Medical Advertisements Ordinance (UMAO)

The value of reference books and subscriptions must be provided on an infrequent basis and limited to HK\$8,000 per hospital department or group practice per year. Other informational or educational items must be of modest value.

(b) Items of Medical Utilities

Items of medical utility may be offered or provided to HCPs if such items are of modest value, do not offset routine business practices and are beneficial to enhancing the provision of medical services and patient care.

Items of medical utility, such as anatomical models, patient starter kits and demo devices, 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.

## **7. MEDICAL REPRESENTATIVES**

- 7.1 Medical representatives should be adequately trained and possess sufficient medical and technical knowledge to present information on the member company's products in an accurate, ethical and responsible manner.
- 7.2 Medical representatives should at all times maintain a high standard of ethical conduct in the discharge of their duties.
- 7.3 The requirements of the Code including accuracy, objectivity, fairness, balance and good taste apply to oral presentations as well as printed or digital material.
- 7.4 Unfair or misleading comparisons or comparisons implying a therapeutic advantage that is not in fact justified should not be made by medical representatives. Promotional communications should have medical clearance by the responsible person before their release.
- 7.5 Medical representatives should not employ any inducement or subterfuge to gain an interview. No payment of a fee should be made for the grant of an interview.
- 7.6 Medical representatives should take adequate precautions to ensure the security of pharmaceutical products in their possession. They should also report to their company any information that they receive on the use of products and particularly reports of side effects.
- 7.7 Member companies should prepare detailed briefing material for medical representatives on the technical aspects of any product that the medical representative is to promote.
- 7.8 The system of remuneration of medical representatives should not be such as to adversely influence the proper prescribing of pharmaceutical products by the doctor.

- 7.9 Medical representatives should not copy and distribute to HCPs any briefing materials including training material or in-house and internal memo product material for promotion purposes without the prior approval of the responsible person in the member company – see Section 3.9.
- 7.10 As the definition of medical representatives as stated in Section 2.5 encompasses staff from any department of member companies, whether or not a particular staff can be engaged in promotional and/or non-promotional activities should be clearly defined in their job scope.

## **8. SAMPLES**

Sample packs should only be used to familiarize doctors with the medicine in clinical practice.

Sample provision must be decoupled from any acts to recommend, purchase, supply, sell, administer or obtain formulary listings of medicines.

Drug samples submitted for tender bidding, registration and quality assurance are out of scope.

- 8.1 Each sample pack should be clearly indicated as such (e.g., “doctor sample, not for sale”). The frequency and volume of samples provision should be reasonable given the doctor’s experience with the product and in any event, limited both in quantity and face value. A reasonable interpretation of such limitation with reference to international practices is that:
- (a) Each department of a hospital or clinic receives samples for a maximum of 6 months from the first date of sample delivery. (This applies to Hong Kong only).
  - (b) Under no circumstances shall samples be included or used as part of any sale and purchase transaction of any product. Samples should not be provided after the department/clinic has started purchasing the product.
- 8.2 Samples should only be given out in accordance with applicable policies of healthcare institutions (e.g. Hospital Authority)
- 8.3 Where samples of products restricted by law to supply by prescription or classified as “Prescription Drug” or “Drug under Supervised Sales” are distributed by a representative, the sample should be handed directly to a doctor, dentist or pharmacist, or someone authorised by such a person to receive the sample on his or her behalf. A receipt bearing the doctor, dentist or pharmacist’s signature must be obtained for the quantity of samples supplied.
- 8.4 In order to comply with Section 8, member companies should maintain proper records and sample receipts so as to show a reconcilable balance.

## **9. GRANTS AND DONATIONS**

### 9.1 General Principles

- (a) Grants and donations collectively means financial and non-monetary awards, such as products, equipment, services or employee’s time or other assets.
- (b) Grants or donations must never be given to individual HCPs.

- (c) Grants and donations must be made with full transparency. Member companies shall require the recipient organization to provide meaningful acknowledgement or disclosure of the support that it received.
- 9.2 Grants and Donations to a Healthcare Organization (HCO) or Medical Society
- (a) Grants and donations to HCOs or Medical Societies must be made in writing and with a legitimate purpose (e.g. for research or educational purpose).
  - (b) Grants and donations to HCOs or Medical Societies shall not be made with the intention of receiving in exchange any direct benefit or preferential treatment, of obtaining or retaining business or a commercial advantage.
  - (c) Grants and donations to HCOs or Medical Societies are allowed when they can demonstrate clear benefit to public institutions or patients and provided that the support does not subsidize routine activities or operations of any medical practice.
  - (d) The amount of the grant or donation to HCOs or Medical Societies should be proportionate to the purpose for which it is made and should not be considered or perceived excessive according to the judgment of a reasonable person.

## **10. MARKETING RESEARCH**

- 10.1 Methods used for marketing research should never be such as to bring discredit upon, or to reduce confidence in the pharmaceutical industry. The following sections apply whether the research is carried out directly by the member company concerned or by an organisation acting on the member company's behalf.
- 10.2 Marketing research should not in any circumstances be used as a disguised form of sales promotion and the research per se should not have an objective of the influencing the opinions of the informant.
- 10.3 The identity of an informant should be treated as confidential, unless he or she has specifically agreed otherwise. In the absence of an agreement, the information provided (as distinct from the overall results of the research) should not be used as the basis upon which a subsequent approach is made to that informant for the purpose of sales promotion.
- 10.4 Precautions should be taken to ensure that no embarrassment results for informants following on from an interview, or from any subsequent communication concerning the research project. Any compensation offered to the participants should be kept to a minimum, and be commensurate with the work involved.

## **11. CLINICAL RESEARCH AND TRANSPARENCY**

### 11.1 Transparency

Member companies are committed to the transparency of clinical trials that they sponsor. It is recognized that there are important public health benefits associated with making clinical trial information more publicly available to HCPs, patients, and others. Such disclosures, however, must ensure protection for individual privacy, intellectual property and contract rights, as well as conform to legislation and current national practices under patent law.

Member companies should only disclose clinical trial information as set out in the Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases (2009) or equivalent.

#### 11.2 Distinct from Promotion

All human subject research (including clinical trials and observational studies) must have a legitimate scientific purpose and must not be used as a disguised form of sales promotion.

### **12. RELATIONS WITH THE GENERAL PUBLIC AND LAY COMMUNICATION MEDIA**

- 12.1 Requests from individual members of the public for information or advice on personal disease and/or medical matters must be refused and the enquirer should be recommended to consult trained persons, doctors or pharmacists.
- 12.2 Information about pharmaceutical products that is made available to the general public, both directly or indirectly, must be factual and presented in a balanced way. It must not raise unfounded hopes of successful treatment or be misleading with respect to the efficacy and safety of the product. In addition, information about pharmaceutical products that is made available to the general public, including during activities organized for the general public, must comply with all local laws and regulations such as the Undesirable Medical Advertisements Ordinance (UMAO).
- 12.3 Disease awareness materials presented to the general public is for the purpose of public health education and is non-promotional. Member companies should ensure that the implications of the disease are presented in a balanced and fair manner and do not unduly emphasize particular options or the need to seek treatment. Member companies should ensure public communications of prescription medicines should not induce patients to seek for a particular type of treatment or medicine and must comply with the UMAO.
- 12.4 Member companies should disclose their identities, roles and responsibilities when organizing activities for the general public, such as “users’ support group” and “patient education provider”. When funding media programmes, member companies should clearly disclose their identities and roles in the programmes to the audience e.g. programmes in which medical bodies endorse certain treatment concepts.
- 12.5 All personal information collected should be treated and maintained sensitively and should not be used to solicit the use of pharmaceutical products. Only necessary personal information should be collected for a purpose directly related to its function or activity. No use of the personal information collected is allowed unless with the person’s prior consent as appropriate. Each member company shall have in place a personal data management policy and procedures which comply with the applicable laws of the City, such as the Personal Data (Privacy) Ordinance.

### **13. INTERACTIONS WITH PATIENTS AND PATIENT ORGANIZATIONS**

- 13.1 The Code is centered on trust to act with integrity and honesty to improve patient care and build trust with those we serve and to respect the independence of patients, patient organizations and other stakeholders.

The pharmaceutical industry has many common visions on patient benefits with patient organizations. All interactions with patient organizations should be



conducted in full respect of medical ethical values and should aim to have a positive impact on the overall healthcare system.

- 13.2 The key principles of interactions with patients and patient organizations are clarity of purpose, independence, respect, privacy, transparency and integrity. Member companies should interact with patients and patient organizations with a clear purpose consistent with applicable laws, regulations, and industry codes of practice. The independence and privacy of patients and patient organizations must be respected.

A written agreement of the objective and scope of any financial relationship should be in place insofar as practicable but if not practicable, written documentation evidencing such is the minimum requirement.

- 13.3 When working with patient organizations, member companies must ensure that their involvement and the nature of that involvement is clear from the outset. No member company may request that it be the sole funder of a patient organization or any of its major programs. Member companies should avoid being the majority annual funder of a patient organization.
- 13.4 Companies that provide financial support or benefit-in-kind contributions to patient organizations must have in place written documentation evidencing an agreement setting out the nature of the support, including the purpose of any activity and its funding. All benefits must be for a legitimate purpose, decided in accordance with an established governance structure of member companies, fully transparent, properly documented, accounted for and should be meaningfully disclosed in a manner that provides reasonably adequate information of member company's support and/or collaboration at the occasion of the relevant event.
- 13.5 Member 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 member companies hold meetings for patient organizations, member companies must ensure that the venue and location is appropriate and conducive to the information communicated. In addition, any meals or refreshments provided by a company must be modest as judged by local standards. Member companies' support for patient organizations' events and meetings should generally be consistent with standards applicable to HCPs.

#### **14. COMPLAINT PROCEDURE**

A complaint procedure has been established to provide a mechanism for member companies and HKAPI to deal with suspected or actual breaches of the Code by other member companies. However, the Code has an equally, if not more important role in encouraging the implementation and self-monitoring of member companies' practices and conduct in order to mitigate against issues that may lead to breaches of the Code. Member companies involved in any dispute are therefore encouraged to seek resolution amicably, including through direct communications between the General Managers/Presidents/Heads of the respective member companies with mediation support by HKAPI. Nonetheless, member companies may file a complaint to the Code of Practice Committee ("CPC") at any point in time during a dispute, regardless of whether the parties have attempted to resolve the dispute amicably or not.

Complaints escalated to HKAPI by anonymous sources, the general public, and non-member companies are not subject to this complaint procedure and will be handled separately on a case-by-case basis at the discretion of the HKAPI Executive Director. Likewise, complaints raised by member companies against non-member companies are

outside the scope of this complaint procedure and will be handled separately by the HKAPI Executive Director.

- 14.1 The member complaint resolution process is administered by the CPC for which the Executive Director shall invite 3 members, who should generally be Directors, General Managers or Managing Directors of members companies. The Executive Director may also invite members (e.g. medical staff) or other external stakeholders (e.g. subject matter experts, including physicians, lawyers, etc.) who have specific knowledge or expertise that is relevant to and can help efficiently resolve a dispute.

Provided that they have valid reasons/justification, the companies involved in the complaint have the right to reject an individual to be included in the panel of the CPC within 7 days of its formation.

If, after best efforts, the parties and the Executive Director still cannot reach an agreement on the CPC panel composition, the Executive Director will elevate the issue to the Board of Directors for final resolution.

The CPC shall have the authority to appoint a Chairman of the CPC. Decisions are made by a simple majority of the CPC, with the Chairman having a casting vote.

- 14.2 (a) The HKAPI complaint procedure is open only to member companies acting in good faith within the spirit and intentions of the Code.
- (b) All correspondence should be addressed to the HKAPI.
- (c) All complaints about any one activity should to the extent practicable be made at one time.
- (d) Complaints must be in writing and for each case THE COMPLAINANT should:
- (i) identify him or herself and his or her member company with a full mailing address, email address, telephone number, and fax number (if available), for correspondence.
  - (ii) identify the company or companies which is alleged to be in breach of the Code (THE RESPONDENT), and the name of any company personnel, product or products which are specifically involved.
  - (iii) indicate whether attempts have been made to resolve the matter directly with the company alleged to have breached the Code.
  - (iv) give the source of the activity which is alleged to be in breach of the Code.
  - (v) give the date of the alleged breach of the Code which must have occurred during the last twelve months from the date of the complaint.
  - (vi) specify the individual elements in any activity which is alleged to be in breach of the Code.
  - (vii) specify for each element which section(s) of the Code is/are alleged to have been breached.
  - (viii) give the reason(s) for the complaint.

- (ix) provide supporting evidence of the alleged breach(es).
  - (e) The Respondent should provide reasons with supporting evidence that the Code has not been breached.
  - (f) The CPC shall render a decision within 30 calendar days of receipt of all necessary information and supporting documentation, including the Complainant and the Respondent's response under Sections 14.2 (d) and (e) and shall promptly notify the respective parties of its decision, and the reasons therefor, in writing and via email. The CPC may conduct its review in any manner it thinks fit. If necessary, the CPC can ask the Complainant or the Respondent for additional information, in which case the above 30-day timeline may be extended.
  - (g) Although there is no upfront fee to file a complaint, once a formal complaint is filed through this process and the CPC is formed to investigate the issue, the Complainant may not withdraw the complaint without the Respondent's written consent. If the Complainant withdraws the complaint without the Respondent's written consent, the Complainant will be responsible for paying an administration fee of HK\$20,000 for escalating a complaint without merit.
- 14.3 The decision of the CPC shall be final and binding and adherence to the decision shall be a condition of continued membership of the HKAPI. The losing Respondent found to have breached the Code shall be responsible for a penalty fee of HK\$100,000 whereas the losing Complainant will be responsible for an administration fee of HK\$20,000. To this end, payment to HKAPI by the losing party should be made within 14 calendar days of the CPC's decision. In addition, at the discretion of the Board of Directors (excluding any Director with an actual or potential conflict of interest), the decision of the CPC may be sent to the regional office, headquarters and/or other affiliates of the Respondent company found to be in breach.
- 14.4 If the CPC concludes that there has been a breach of the Code, the Respondent shall be asked to provide a written undertaking to immediately cease and refrain from any such activity contrary to the Code now and in the future. In addition, information is required on the action that has been taken or will be taken to remedy the matter.
- 14.5 (a) In the event that a complaint regarding any breach of the Code is upheld by the CPC, in addition to the aforementioned penalty under Section 14.3, the Respondent may be suspended or expelled from HKAPI membership for any period of time as the Board of Directors after having the chance of reviewing CPC's decision (excluding any Director with an actual or potential conflict of interest as aforesaid) deem fit.
- (b) A repeated violation of the Code within three (3) years (from the date of CPC decisions after the effective date of this updated Code) (hereinafter the 3-year period) will be treated as a new violation and the provisions of Section 14.6 will apply. In addition, the amount of penalty fee payable by the losing Respondent for a repeated violation during the 3-year period shall be the annual subscription fee of the current calendar year by the losing Respondent or HKD100,000 (whichever is higher) times the number of repeated violations during the 3-year period. Further, the Board of Directors after having the chance of reviewing CPC's decision (excluding any Director with an actual or potential conflict of interest as aforesaid) may exercise the discretion to lengthen the duration of the suspension, or expel the losing Respondent with repeated violations during the 3-year from HKAPI.

- 14.6 The HKAPI shall produce an annual report (January – December inclusive) summarising the complaints received and the final decision on all complaints. This report will be distributed to the members of the HKAPI and relayed to such other interested parties or bodies as the Board of Directors may decide such as the headquarters and affiliates of the company found to be in breach, the Food and Health Bureau, the Department of Health, the Hospital Authority, medical societies and the Consumer Council.

In the event of a grave and serious or repeated breach of the Code which is of public interest, the Respondent company (and product, where relevant), the country/market in which the incident took place, and a summary of the key facts of the case will be immediately made public on the HKAPI website. In addition to the applicable penalty under Sections 14.3 and 14.5 above, a summary of such a breach will be sent to HKAPI members and, at the discretion of the Board of Directors (excluding any Director with an actual or potential conflict of interest), the Food and Health Bureau, the Department of Health, the Hospital Authority, medical societies and the Consumer Council etc..

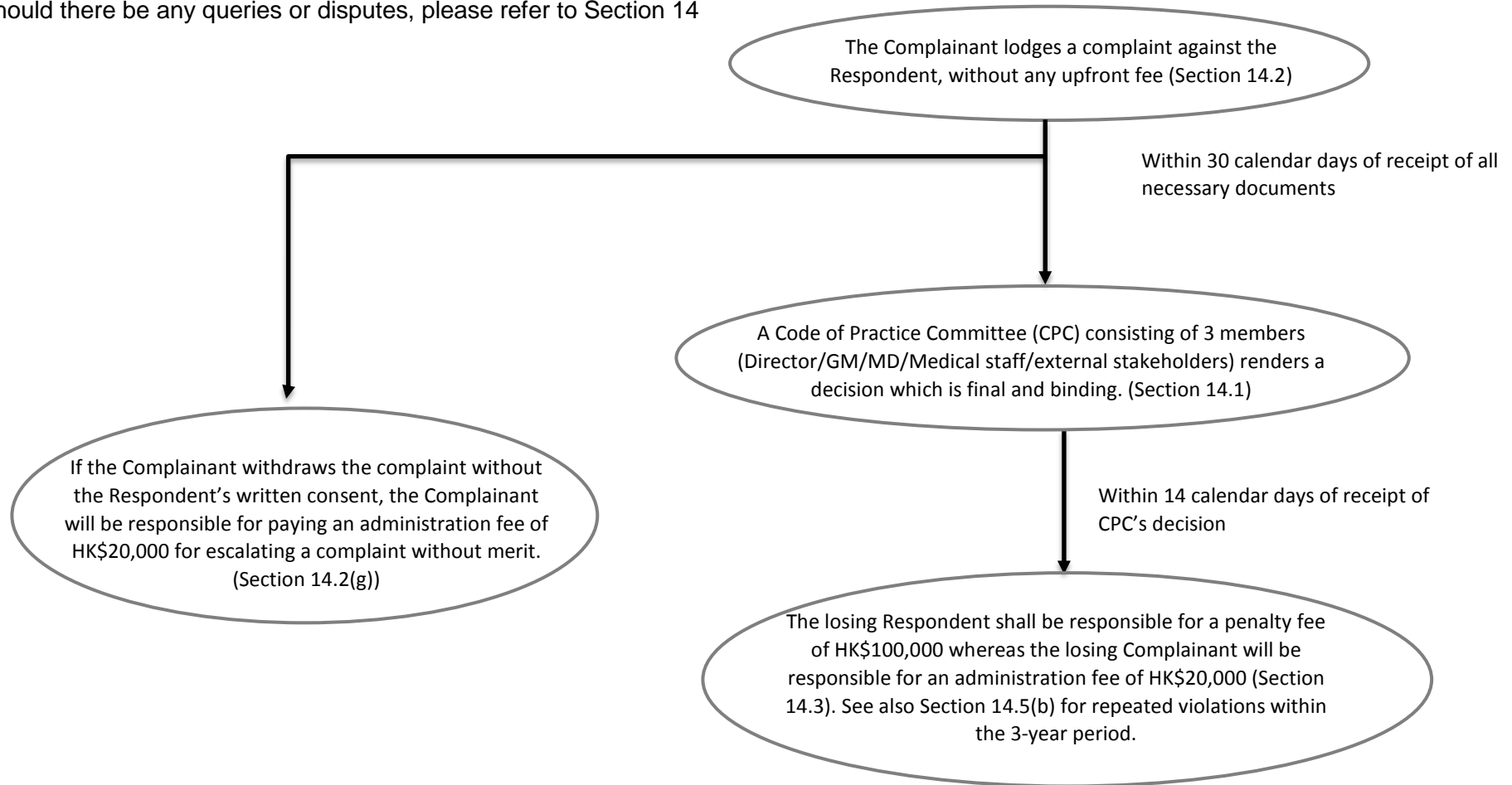
- 14.7 Member companies agree that they will follow the dispute resolution procedures in Section 14 of the Code to adjudicate on any local dispute or complaint in relation to violation of the Code that may arise, and the Code shall have exclusive jurisdiction over such local dispute or complaint between member companies.
- 14.8 Notwithstanding Section 14.7, on local issues that are not stipulated in or regulated by the Code, and/or international issues that go beyond the boundaries of one local country/market: (1) the member companies may refer such issues to IFPMA for dispute resolution if they cannot be resolved by HKAPI despite reasonable effort being made; and/or (2) the HKAPI may refer such matters to the IFPMA for adjudication if required.

## **15. EFFECTIVE DATE**

This Twenty First (21<sup>st</sup>) Edition of the Code shall take effect on 7<sup>th</sup> October, 2022 and supersedes previous editions.

## Appendix 1 - COMPLAINT PROCEDURE

Should there be any queries or disputes, please refer to Section 14



## **Appendix 2**

Guidance on the meanings of the terms “nominal” and “reasonable” as used in Sections 5.1(d), 5.3(h), and 6.2 of the Code, for activities taking place in Hong Kong and/or Macau.

### **Under Section 6.2**

1. “Nominal” means a maximum of HK\$150 per item for the promotion of over-the-counter medicine.

### **Under Sections 5.1(d) and 5.3(h) as appropriate**

2. “Reasonable” means a maximum of, during or following an Event with local HCPs:

HK\$400 per attendee for breakfast or for lunch, and a maximum of HK\$800 per attendee for dinner (excluding service charges/gratuities or incremental costs attributable to venue rental where necessary and identifiable), excluding allowable hospitality as outlined in Sections 5.1(d) and 5.3(h). For meals provided during Events taking place overseas, the value should be reasonable by local standards in the relevant country/market and to the extent possible at a level comparable to the amount allowable in the City.

THE ASSOCIATION WISHES TO DRAW THE ATTENTION OF MEMBERS TO DEALINGS WITH PUBLIC SERVANTS EMPLOYED BY THE GOVERNMENT AND PUBLIC BODIES, WHO ARE PROHIBITED FROM SOLICITING OR ACCEPTING ADVANTAGES UNDER THE PREVENTION OF BRIBERY ORDINANCE CAP. 201. THERE ARE ALSO RESTRICTIONS ON THE ACCEPTANCE OF ENTERTAINMENT BY THESE PUBLIC SERVANTS.

**THE CODE OF PRACTICE  
WAS ADOPTED BY THE CURRENT MEMBERSHIP OF  
THE HONG KONG ASSOCIATION OF THE PHARMACEUTICAL INDUSTRY  
October 2022**

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