

Effective from 1 Jan 2019

HKAPI CODE OF PRACTICE

19th edition, 2019

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 Macao 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. 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. Interactions with healthcare professionals 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.

All members – be they full 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.

INTRODUCTION

- I. We, the members of the HKAPI, including full 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 Macao Special Administrative Regions (hereafter referred to as “Hong Kong” and “Macao” 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 Macao, 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 with healthcare professionals (HCPs) are intended to benefit patients and to enhance the practice of medicine. Interactions should be focused on informing HCPs about products, providing scientific and educational information and supporting medical research and education.

- 1.2 No financial benefit or benefit-in-kind (including but not limited to grants, scholarships, subsidies, support, consulting contracts or educational or practice related items) may be provided or offered to a HCP 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.
- 1.3 Promotion should encourage the appropriate use of pharmaceutical products by presenting them objectively and without exaggerating their properties.
- 1.4 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 material or events in any specific city.
- 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 those informational and marketing activities including audio-visual materials created by a pharmaceutical company or with its authority, with the intention of ensuring proper and rational use, supply or administration of its pharmaceutical products.

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 "reminder promotion" means a short advertisement targeting HCPs containing no more than the brand names or brand and generic names, 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).

- 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.

3. GENERAL PROVISIONS APPLICABLE TO THE CODE

- 3.1 Marketing practices should never bring discredit upon the pharmaceutical industry.
- 3.2 Information in promotional material 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.

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) 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) 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. 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.

4. METHODS OF PROMOTION TO HEALTHCARE PROFESSIONALS

- 4.1 All promotional materials, excluding reminder promotions (refer to Section 2.1), issued for promotional purposes by the manufacturer or with the manufacturer's 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 The same requirements as applied to printed materials shall apply to digital promotional materials. 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

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, pharmaceutical 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 pharmaceutical 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 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 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 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 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 paragraph 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. 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, 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 paragraph 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 paragraph 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) 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 associations 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 paragraphs 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, EDUCATIONAL ITEMS AND ITEMS OF MEDICAL UTILITY

- 6.1 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 either directly or through clinics or institutions.

Gratuitous payments in cash or cash equivalents (such as gift certificates, free flight upgrades) must not be offered to HCPs under any circumstances.

- 6.2 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 Informational or educational items provided to HCPs for their education or for the education of patients on disease and its treatments may be offered by member companies provided that the items are primarily for educational purposes.

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.

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.

- 6.4 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 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 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 company – see Section 3.9.

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, 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 paragraphs apply whether the research is carried out directly by the company concerned or by an organisation acting on the 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 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.

12.4 All personal information collected should be treated and maintained sensitively and should not be used to solicit the use of pharmaceutical products. No use of the personal information collected is allowed unless with the person’s prior written consent. Each member company shall have in place a personal data management policy and procedures which comply with the applicable laws of the City.

13. INTERACTIONS WITH PATIENT ORGANIZATIONS

13.1 Patient organizations are typically not-for-profit institutions that primarily represent the interests and needs of patients, their families and / or caregivers.

The pharmaceutical industry has many common interests with patient organizations. All interactions with patient organizations must be ethical. The independence of a patient organization must be respected.

13.2 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.

13.3 Companies that provide financial support or benefit-in-kind contributions to patient organizations must have in place written documentation setting out the nature of the support, including the purpose of any activity and its funding. All benefits must be fully transparent, properly documented, accounted for and should be disclosed whenever required.

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

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 Country/General Managers 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 himself 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 Paragraphs 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. If the Complainant withdraws the complaint, the Complainant will be responsible for paying the penalty 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 party, whether it is an unsuccessful Complainant or the Respondent found to have breached the Code, shall be responsible for the penalty 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.
- 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 fee, the Respondent may be suspended or expelled from HKAPI membership for any period of time as the Board of Directors (excluding any Director with an actual or potential conflict of interest as aforesaid) deem fit.
- (b) A repeat violation of the Code will be treated as a new violation and the provisions of paragraph 14.6 (a) will apply, subject to the discretion of the Board of Directors to increase the amount of fine of up to HK\$100,000, lengthen the duration of the suspension, or expel the Respondent company from HKAPI.
- 14.6 (a) 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.

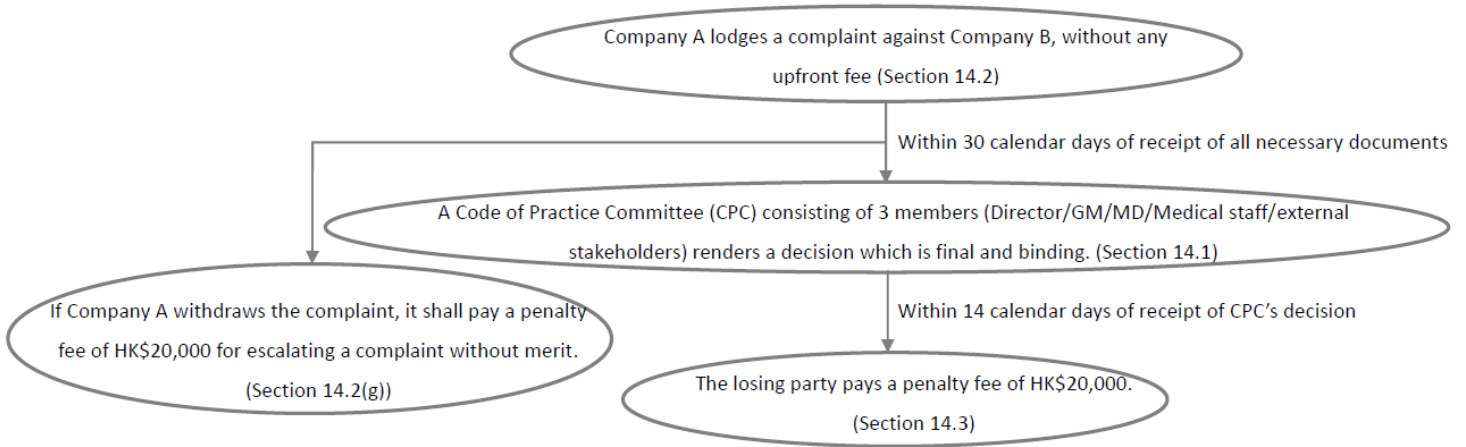
In the event of a grave and serious breach of the Code which is of public interest, the Respondent company (and product, where relevant), the country in which the incident took place, and a summary of the key facts of the case will be immediately made public on the HKAPI website. A summary of such a 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), to the headquarters and affiliates of the Respondent company found to be in breach, the Food and Health Bureau, the Department of Health, the Hospital Authority, medical societies and the Consumer Council immediately after the expiry of all channels of appeal.

- 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: (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 Nineteenth Edition of the Code shall take effect on 1st January, 2019 and supersedes previous editions.

Complaint Procedure



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

Appendix

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

Under Paragraph 6.2

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

Under Paragraph 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 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