HKAPI CODE OF PRACTICE

18th edition, 2017

PREAMBLE

The Hong Kong Association of the Pharmaceutical Industry ("HKAPI") was formed in 1968 with a mission to drive the expedient access of 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 expectation 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 decision in their conduct of professional work. It also serves as a basis for judging formal complaint with respect to our professional ethical standards.

Member companies are abided by The Code not just by words, but also its 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, affiliate or associate members - of the Hong Kong Association of the Pharmaceutical Industry, oblige to observe The Code to achieve and maintain uniformly high professional and ethical standards across the industry, as we are committed to the improvement of the health of mankind through production, research, development and distribution of pharmaceutical products.

INTRODUCTION

I. WE, THE MEMBERS OF THE HONG KONG ASSOCIATION OF THE PHARMACEUTICAL INDUSTRY, including Full Members, Affiliate Members and Associate Members, being committed to the improvement of the health of mankind through the research, development, production and marketing of pharmaceutical products of reliable quality, in accordance with internationally defined standards of good practice, and being aware of our responsibilities in providing accurate information on our products.

II. 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 code of practice should be consistent with high ethical standards and that information should be designed to help improving 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. AND ACCORDINGLY, to ensure that these responsibilities and principles are fulfilled, WE ADOPT this Code of Practice “(hereinafter referred to as ‘the Code’)” for our activities in Hong Kong and Macau, which indicates acceptance of, and embodies the principles set out in the IFPMA Code of Pharmaceutical Marketing Practices 2012 edition (“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 are intended to benefit patients and to enhance the practice of medicine. Interactions should be focused on informing healthcare professionals about products, providing scientific and educational information and supporting medical research and education.

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 healthcare professional 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 healthcare professional’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 by whom it has been

sponsored.

1.6 Substantiated information on serious and unexpected adverse reactions associate 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 this Code shall apply to the dealings of medical devices and nutritional productions by Member companies to the extent applicable.

2. DEFINITION OF CERTAIN TERMS FOR PURPOSE OF THE CODE

2.1 The term 'promotion' means those informational and marketing activities including audio-visual material, undertaken by a pharmaceutical company or with its authority, the purpose of which is to ensure proper and rational use, supply or administration of its pharmaceutical products.

It includes the activities of representatives and all other aspects of sales promotion in whatever form, such as journal and direct mail advertising; participation in exhibitions; the use of audio-cassettes, films, records, tapes and video recordings, the use of Internet, digital media, viewdata systems and data storage devices such as memory discs accessed and reproduced on television apparatus, visual display units and the like; the provision of samples, gifts and hospitality.

2.2 The term 'pharmaceutical product' in this concept means any pharmaceutical or biological product intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans, or to affect the structure or any function of the human body, which is promoted and advertised to the healthcare professionals 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 terms 'healthcare professional' should be interpreted to extend to medical, dental, pharmacy, nursing and/or other para-medical professions including students or trainees in all such related disciplines, who in the course of his or her professional activities may prescribe, recommend, purchase, supply or administer a pharmaceutical product.

2.4 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.

2.5 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 or substance, and any subsequent amendments.

3. GENERAL PROVISIONS APPLICABLE TO THE CODE

3.1 Marketing practices should never be such as to 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 such information should be accurate, objective, fair, 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 as to pharmaceutical products’ safety, contraindications and side effects or toxic hazards is appropriately and consistently communicated subject to the legal, regulatory and medical practices of the City.

3.4 Disparaging reference to other products or manufacturers should be avoided.

3.5 Comparative claims should be well founded on data from adequate and well controlled clinical studies and should be consistent with the evidence of other clinical data.

(a) Non-clinical comparative studies on antibiotics are acceptable provided the tests are well-established scientific and evident based standards activity 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 law and to review and monitor all of

their promotional activities and materials.

(b) Companies should also ensure that relevant employees receive training appropriate to their role.

(c) Promotional communications, whether in Chinese or English, should have medical clearance or, when appropriate, 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 Promotional material, such as mailings and medical journal advertisements, should not be such as to disguise its real nature.

3.9 No pharmaceutical product shall be promoted for use in the City until the requisite approval for marketing for such use 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 a pharmaceutical product, including appropriate dissemination of investigational findings in scientific or lay communications media and at scientific conferences. Nor should it restrict public disclosure to stock holders and others concerning any pharmaceutical product as may be required or desirable under law, rule or regulation.

3.10 Promotion should be capable of substantiation either by reference to the approved labeling 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 are appropriate to the source of the inquiry.

4. METHODS OF PROMOTION TO HEALTHCARE PROFESSIONALS

4.1 All material (including journal advertising and Internet posting) which is issued for promotional purposes by the manufacturer or with his authority should include the following:-

(a) The name of the product (normally the brand name);

(b) The name, address, telephone and fax numbers of the manufacturer or his authorised agent, or the business name and address of the part of his 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) At least one authorised indication for use consistent with the prescribing information.

(e) 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.

(f) Information provided in (a) to (e) must be up-to-date and valid according to the respective registration details in the applicable City.

4.2 The word ‘new’ in relation to a product, indication or presentation should only be used during the first 12 months of promotion of that product, indication or presentation.

4.3 The term “Reminder” means, for the purpose of the Code, a promotional material containing no more than a simple statement of indications to designate the therapeutic category of the product. Except for pharmaceutical products where use entails specific precautionary measures, Reminders need not contain all the prescribed information under Paragraph 4.1 above, provided that the generic name of the product is given and that a form of words is used which indicates clearly that further information is available on request. Reminder promotion is considered to be that for a product which has been on sale for a period of not less than 12 months.

4.4 Promotional material should conform, both in text and illustration, to canons of good taste and should recognise the professional standing of the recipients.

4.5 Where appropriate, for example, in technical and other informative material, the year and the month of printing or last review should be indicated on the material.

4.6 In a multi-page promotional material, only one page needs to include the information required by Paragraph 4.1 of the Code; provided that each of the other pages (except the page on which, or facing which, the information is printed) includes a reference, indicating on which page that information appears.

4.7 The same requirements as applied to printed materials shall apply to electronic 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 shall not be inconsistent with this 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, congress and other communications means

When a pharmaceutical company or association 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 finish 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 healthcare professionals (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) The fact of sponsorship by the company or association should be clearly stated in advance, at the meeting and in any proceedings. Printed, audiovisual or computer-based 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) Save and except under paragraph 5.3(i), 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 in any event, limited to travel, meals, accommodation and genuine registration fees;

(e) Any support to individual healthcare professionals 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 healthcare professionals 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 to extend any travel or other sponsorship to 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 or meeting. 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 healthcare professionals to attend Events provided such sponsorship is in accordance with the following requirements:

(a) The Event complies with the hospitality requirements in this Code;

(b) Sponsorship to healthcare professionals 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 healthcare professionals for time spent in attending the Event;

(d) Any sponsorship provided to individual healthcare professionals 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 healthcare professionals.

(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 it is 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”, “modest” and “reasonable” as used in paragraphs 5.1(d), 5.3(h) and 6.2 of this Code.

(h) No stand-alone entertainment or other leisure or social activities should be provided or paid for by member companies at Events, except that entertainment of modest nature by reasonable local standards which is incidental to refreshments and/or meals is allowed, or any other exceptions as stated in the Appendix. It is allowable for Event participants (including representatives from member companies) to pay for any stand-alone entertainment or other leisure or social activities on their own that occur outside of the Event agenda, in good taste and shall not bring the industry or any member company into disrepute.

5.4 Fees for Services

Health care professionals may be engaged as consultants and advisors for services such as speaking at and/or chairing meetings and events, involvement in medical/scientific studies, clinical trials or training services, participation at advisory board meetings, and participation in market research where such participation involves remuneration. The arrangements which cover these genuine consultancies or other services must, to the extent relevant to the particular arrangement, fulfill 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 healthcare professional’s principal) must be fulfilled 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 medicine; and

(f) the compensation for the services includes the fair market value of the services provided according to where the healthcare professional (HCP) practices, and

(g) whenever applicable, the reimbursement of out of pocket expenses including travel and accommodation that must be reasonable by the locality’s standards. These should be included in the compensation arrangements and documented.

6. HOSPITALITY, PROMOTIONAL 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 healthcare professionals.

6.2 Promotional items of nominal value, provided free of charge and on infrequent basis, are permissible as long as they are related to the healthcare professional's practice and/or entail a benefit to patients.

6.3 Text, reference-books, electronic books, magazines, journals, or other items, scientifically and/or medically-related and/or educational in nature, may only be given to hospitals or private group practices provided that they serve a genuine educational purpose, are provided on infrequent basis and limited to HK$8,000 per hospital department or group practice per year. Maximum expenditure of these items per company should be in a modest amount in a calendar year.

6.4 Gratuitous payments in cash or cash equivalents (such as gift certificate, free flight upgrade) must not be offered to healthcare professionals under any circumstances.

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 which aim at accuracy, objectivity, fairness, balance and good taste apply to oral presentations as well as printed or electronic material.

7.4 Unfair or misleading comparisons or comparisons implying a therapeutic advantage which 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 which 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 which the medical representative is to promote.

7.8 The system of remuneration of 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 healthcare professionals detail briefing material which can be 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 packs are decoupled from any acts to recommend, purchase, supply, sell, administer, or formulary listings of medicines.

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

8.1 Each sample pack should be clearly indicated as such (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 size 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 further provided after the department/ clinic has started purchase of the product.

8.2 Samples shall 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 on prescription or are 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 All samples should be stored in a locked and secure area in accordance with the Department of Health's storage requirements and someone should be assigned to be responsible for the procedures relating to the storage and balance of such samples. Companies should keep 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 finance awards and non-monetary awards, such as products, equipments, 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 Healthcare Organization (HCO) or Medical Society

(a) Grants and donations to Healthcare Organizations (meaning any private or public sector organization, institution or association that is comprised of HCPs and/or that provides healthcare services, including a clinic or medical practice consisting of three or more HCPs) and 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 by 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 as a direct objective the influencing of the opinions of the informant.

10.3 The identity of an informant should be treated as being confidential, unless he has specifically agreed otherwise. In the absence of this agreement it follows that the information provided (as distinct from the overall results of the research) 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 which they sponsor. It is recognized that there are important public health benefits associated with making clinical trial information more publicly available to healthcare practitioners, patients, and others. Such disclosure, however, must maintain 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 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 disease or personal medical matters must be refused and the enquirer recommended to consult trained persons, doctors or pharmacists.

12.2 Information about pharmaceutical products which is made available to the general public either 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.

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 disclose prominently to the audience their identities and roles in the programmes, such as programmes in which medical bodies endorse certain treatment concepts.

12.4 All personal information collected pursuant to paragraph 12.1 should be treated and maintained sensitively and should not be used to solicit 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 personal data management policy and the procedures which comply with the applicable law of the City.

13. INTERACTION WITH PATIENT ORGANIZATIONS

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

The pharmaceutical industry has many common interests with patient organizations. All interaction 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 are clear from the outset. No member company may request that it be the sole funder of a patient organization or any of its major program.

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

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 informational communication. In addition, any meals or refreshments provided by a company must be modest as judged by local standards.

14. OPERATING PROCEDURES

The complaint procedure has been established to provide a mechanism for dealing with breaches of the Code. However, the Code has an equally, if not more important role in encouraging the implementation and monitoring of improved standards for practices and conducts in order to prevent the errors which lead to breaches of the Code. Member companies involved in any

dispute are therefore encouraged to seek resolution amicably, through for example direct communications between the Country/ General Manager of the respective member company and mediation by HKAPI. Nonetheless, member companies may file a complaint to the Code of Practice Committee ("CPC") at any point in time during the dispute, regardless of whether the parties have attempted to resolve the dispute amicably or not.

14.1 The Code is administered by the CPC for which the Executive Director shall invite 3 members, who should be the Directors, General Managers or Managing Directors of members companies.

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

If, after best efforts, the two parties and the Executive Director still cannot reach an agreement on the 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 the 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 to any member of the healthcare professions, a company or the public, 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 (whether a company or an individual) with a full mailing address (and fax number, if possible, for correspondence)

(ii) identify the company which is alleged to be in breach of the Code, and the name of any company personnel, product or products which are specifically involved.

(iii) provide evidence that 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 of the date of making 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 company against which the complaint is made (“Respondent”) should provide reasons with supporting evidence that the Code has not been breached.

(f) A charge of HK$10,000 will be payable by the complainant. This does not apply to a person or body outside the pharmaceutical manufacturing industry.

(g) The CPC shall render a decision within 30 calendar days of receipt of all necessary information and supporting documentation, including the complaint and the respondent’s response under Paragraphs 14.2 (d) and (e), and shall promptly notify the parties of its decision, and the reasons therefor, in writing and by registered mail. 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.

(h) The complainant has the right to withdraw its complaint at any time. However, the CPC retains the right to continue investigating the complaint and render a decision, if the CPC in its sole discretion, deems it necessary to do so in the interests of the pharmaceutical industry. The review procedures as set out in Section 14 shall remain available to the respondent should it decide to appeal against the CPC's decision, and HKAPI should become the "respondent in the appeal” If the respondent is not found to have breached the Code, the complainant who initiated the complaint will remain responsible for the initial charge of HK$10,000 despite its subsequent withdrawal of the complaint.

14.3 If a party to the complaint is dissatisfied with the decision of the CPC, it may request for a review of the decision by submitting an appeal to the HKAPI Executive Director in writing within 14 calendar days of receipt of the CPC’s decision. A charge of HK$50,000 will be payable by the appellant, except where the appellant is a person or body outside the pharmaceutical manufacturing industry.

14.4 If no request for a review of CPC’s decision is made within the period specified in Paragraph 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 be an unsuccessful complainant or the respondent found to have breached the Code, shall be responsible for the initial charge of HK$10,000 initially paid by the complainant. To this end, refund to the complainant by HKAPI and payment to HKAPI by the respondent shall be done within 14 calendar days of the CPC’s decision where the CPC concludes there has been a breach of the Code by the respondent. There shall be no refund to the complainant of the charge paid to HKAPI if the CPC decides otherwise.

14.5 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.

14.6 Where a party requests for a review of decision of the CPC as aforesaid, the Executive Director shall select 4 members from member companies and 1 outside expert to convene a Review Committee to review the matter. The cost of such an outside expert shall be borne by the losing party, whether it be an unsuccessful appellant or the respondent in the appeal.

Provided that they have valid reasons/justification, the two companies involved in the complaint have the right to reject an individual member or the outside expert to be included in the panel of the Review Committee within 7 days of its formation. If, after best efforts, the two parties and the Executive Director still cannot reach an agreement on the panel composition, the Executive Director will elevate the issue to the Board of Directors for final resolution.

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

14.7 The Review Committee shall render a decision within 30 calendar days of receipt of the request for a review and promptly notify the HKAPI Executive Director and the parties to the review of its decision, and the reasons therefor, in writing and by registered mail. The decision of the Review Committee shall be final and binding, and adherence to the decision shall be a condition of continued membership of the HKAPI.

14.8 The losing party in the appeal, whether it be an unsuccessful appellant or the respondent in the appeal, shall be ultimately responsible for all charges and fees payable during the complaint proceeding, including but not limited to the initial charge of HK$10,000 and the appeal charge of HK$50,000. To this end, any payment made to HKAPI by the successful party during the complaint proceeding shall be refunded by HKAPI and the losing party shall instead make corresponding payment to HKAPI within 14 calendar days of the Review Committee's decision

14.9 (a) In the event that a complaint regarding any breach of the provisions of the Code is upheld by the CPC or subsequently on appeal by the Review Committee, the company which is judged to have breached the Code will be liable to a fine of up to HK$100,000, or suspended or expelled from HKAPI membership for any period of time as the Board of Directors deem fit (excluding any Director with an actual or potential conflict of interest as aforesaid).

(b) A repeat of the violation of the Code will be treated as a new violation and the provisions of paragraph 14.9 (a) will apply, subject to the discretion of the Board of Directors to increase the amount of fine of up to HK$200,000, or lengthen the duration of suspension or expulsion.

14.10 Where the complainant and/or the company found to be in violation of the Code is a non-member of the HKAPI, the matter will be referred to the Board of Directors for a decision

on whether to impose the penalties referred to in Section 14.9.(a).

14.11 Where the company acknowledges that it has acted in breach of the Code, information is required on the action that has been taken or will be taken to remedy the matter. Where the allegations are rejected, the reasons for rejection must be clearly stated and, where appropriate, supporting data (e.g. scientific evidence to support claims which have been questioned) should be provided.

14.12 (a) The HKAPI shall produce an annual report (April – March 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 e.g. headquarters and affiliates of the company found to be in breach, SCRIP, the Food and Health Bureau, the Department of Health, the Hospital Authority, medical societies and the Consumer Council.

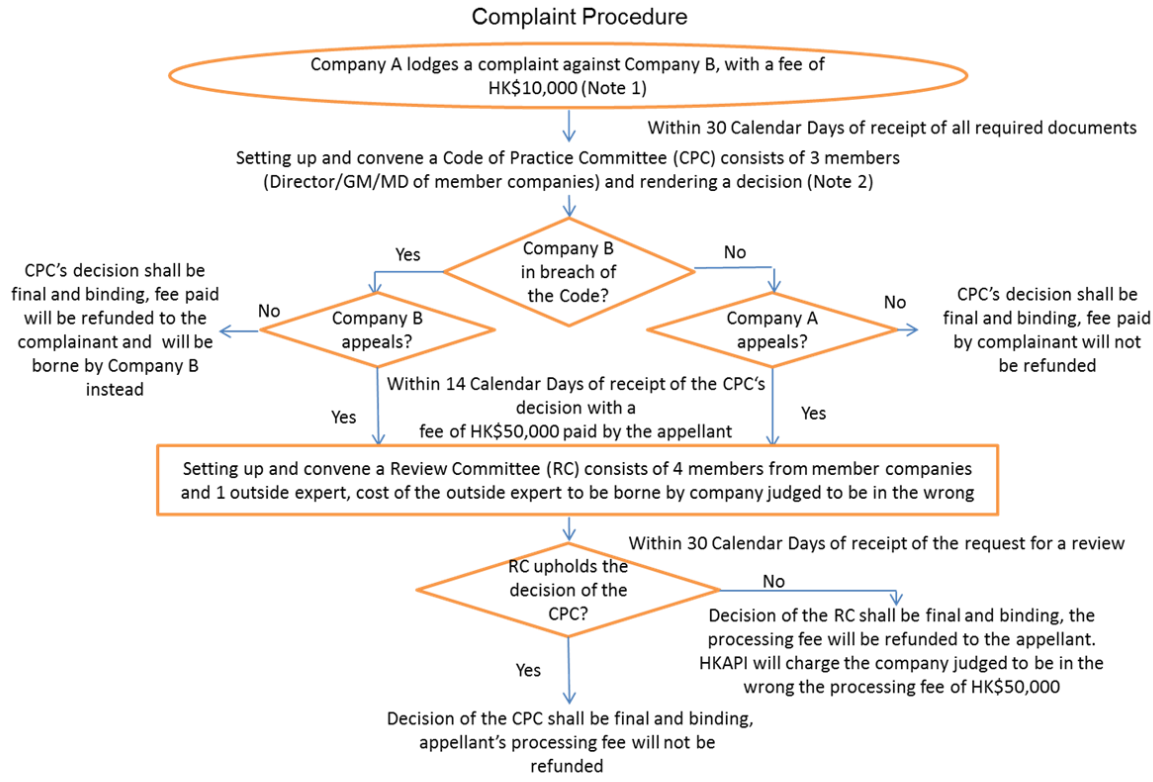
(b) When a complaint is upheld and a breach of the Code is determined, or not disputed by the company, and in the event of a grave and serious breach of the Code which is of public interest, information identifying the company (and product, where relevant) concerned, the country in which the incident took place, the complainant, and providing a summary of the key facts of the case, is immediately made public by publication on the HKAPI website. A summary of such a breach will be sent to members and to 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 immediately after the expiry of all channels of appeal.

14.13 The member companies agree that they shall 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.

14.14 Notwithstanding Paragraph 14.13, on local issue that is not stipulated in or regulated by the Code, and/or international issue that goes beyond the boundaries of one local country: (1) the member companies may refer such issue to IFPMA for dispute resolution if it cannot be resolved within HKAPI despite reasonable effort being made; and/or (2) HKAPI may refer such matter to IFPMA for adjudication in its own initiative.

15. OPERATIVE DATE

This Eighteenth Edition of the Code shall take effect on April 1, 2017 and supercedes previous editions.



Note 1: Please refer to 14.2 for details on the complaint procedure
Note 2: Please refer to 14.1 for details on the setting up of the Code of Practice Committee

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

Appendix

Guidance on the meanings of the terms “Nominal”, “Modest” 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 Macau.

Under Paragraph 6.2

1. “Nominal” means a maximum of HK$150 per promotional item.

Under Paragraph 5.1 (d), 5.3 (h) as appropriate

2. “Modest” means a maximum of:

   HK$700 for condolence flowers for funeral per deceased healthcare professional only. (Condolence flowers to a healthcare professional for deceased family member(s) are not permitted.)

3. “Reasonable” means a maximum of, during or following Event with local healthcare professionals:

   HK$400 per attendee for breakfast or for lunch, and a maximum of HK$700 per attendee for dinner (excluding service charges/gratuity or incremental costs attributable to venue rental where necessary and identifiable), excluding gift per healthcare professional allowable under paragraphs 5.1(d), 5.3(h). For meals provided in Events taking place overseas, the value should be reasonable by local standards in the country in question 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