

MEDICAL DEVICE MARKETING

PRACTICE GUIDELINE

THE HONG KONG MEDICAL AND HEALTHCARE
DEVICE INDUSTRIES ASSOCIATION LIMITED

Edition 4:

Updated on January 1, 2018

HKMHDIA MEDICAL DEVICE MARKETING PRACTICE GUIDELINE

INTRODUCTION

- I. WE, THE MEMBERS OF THE HONG KONG MEDICAL AND HEALTHCARE DEVICE INDUSTRIES ASSOCIATION LIMITED (HKMHDIA), being committed to the improvement of the health of mankind through the research, development, production and marketing of medical and healthcare devices of reliable quality, in accordance with internationally defined standards of good practice, and being aware of our responsibilities in providing the healthcare professionals with accurate information on our products.

- II. WE HAVE PASSED A RESOLUTION TO ACCEPT THE FOLLOWING 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 to health care providers in order to establish a clear understanding of the appropriate use of medical devices, and
 - (b) That marketing practices should be consistent with high ethical standards and that information should be designed to help health care providers improve services to patients. Information should be provided with objectivity, truthfulness, fairness, balanced and in good taste and should conform to all relevant laws and regulations. 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 Medical Device Marketing Practice Guideline “(hereinafter referred to as ‘the Guideline’)” for our activities in the Hong Kong Special Administrative Region.

GENERAL PROVISIONS & DEFINITION OF CERTAIN TERMS

1. DEFINITION OF CERTAIN TERMS

- 1.1 The term ‘marketing’ means those informational and marketing activities including audio-visual material, undertaken by a medical device company or with its authority, the purpose of which is to ensure proper and rational use, supply, maintenance or administration of its medical device.

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, view data 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.

- 1.2 The term “medical device” means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:
- diagnosis, prevention, monitoring, treatment or alleviation of disease,
 - diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
 - investigation, replacement or modification of the anatomy or of a physiological process,
 - control of conception,
- and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;’

For the purpose of the Guideline, medical devices collectively include any in-vitro diagnostic (IVD) medical device. IVD medical device means a device, whether used alone or in combination, intended by the manufacturer for the in-vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes. This includes reagents, calibrators, control materials, specimen receptacles, software, and related instruments or apparatus or other articles.

- 1.3 The terms ‘healthcare professional’ should be interpreted to extend to medical, dental, pharmacy, nursing and/or other para-medical professions, who in the course of his or her professional activities may prescribe, recommend, purchase, supply or use a medical device.
- 1.4 The term ‘medical representative’ means a representative whose duties comprise or include calling upon healthcare professionals.
- 1.5 Instruction-of-use information means comprehensive product information, particularly claims and intended use or purposes, as submitted to and filed with the relevant division of the Department of Health or equivalent authorities in concerned countries or regions including those who are members of Global Harmonization Task Force or Asian Harmonization

Working Party in connection with the listing, registration or conformity assessment of a medical device, and any subsequent amendments.

2. GENERAL PRINCIPLES

- 2.1 Member companies' relationships with healthcare professionals are intended to benefit patients and to enhance the practice of healthcare. Interactions should be focused on informing healthcare professionals about medical devices, providing scientific and educational information and supporting medical research and education.
- 2.2 No financial benefit or benefit-in-kind (including 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 using a medical device 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 and using practices.
- 2.3 Marketing should encourage the appropriate use of medical devices by presenting them objectively and without exaggerating their properties. The use of disparaging remarks to discredit others' products and services are to be avoided.
- 2.4 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 marketing material or events.
- 2.5 Marketing should not be disguised. Clinical assessments, post-marketing surveillance and experience programmes and post-authorization studies must not be disguised marketing. 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 medical devices and their uses, whether marketing in nature or not, which is sponsored by a company should clearly indicate by whom it has been sponsored.
- 2.6 Substantiated information on serious and unexpected adverse reactions associate with medical device should be reported to the appropriate health authority as a priority.
- 2.7 In all matters of application, interpretation and enforcement of any section of the Guideline, it is to be understood that compliance with local laws, regulations and regulatory decisions and requirements will take precedence.

3. GENERAL PROVISIONS APPLICABLE TO ALL MARKETING PRACTICES

- 3.1 Marketing practices should never be such as to bring discredit upon the medical device industry.
- 3.2 Information in marketing 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 Any claim used in marketing material should be documented either by the prescribing information authorized by relevant 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.
- 3.4 All such information should be accurate, objective, fair, balanced and should not be misleading either directly or by implication.
- 3.5 Disparaging reference to other products or manufacturers should be avoided.
- 3.6 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. Non-clinical comparative studies are acceptable provided the tests are well-established scientific and evident based standards activity used in the medical community. Statements based on animal models or in-vitro data must be identified clearly. Such data may be used only if human data are not available. The claimed differences between medical devices should only be made if statistically significant. Comparative statements should mention the comparison medical device. The use of a competitor product brand name requires written consent from that company.
- 3.7 Absolute or all-embracing claims should be used with caution and only with adequate qualification and substantiation. The word 'safe' must not be used without qualification.
- 3.8 Particular care should be taken that essential information as to medical devices' safety, contraindications and side effects or toxic hazards is appropriately and consistently communicated subject to relevant legal, regulatory and medical practices of Hong Kong.
- 3.9 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 marketing activities and materials. Marketing communications, whether in Chinese or English, should have medical clearance or, when appropriate, clearance by the responsible person of Member companies before their release.

- 3.10 When package inserts are printed in Chinese and English, the information imprinted in both languages should be the same.
- 3.11 Marketing material, such as mailings and medical journal advertisements, should not be such as to disguise its real nature.
- 3.12 When appropriate, no medical device shall be promoted for use until the requisite approval for marketing for such use has been given in Hong Kong. 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 medical device, 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 medical device as may be required or desirable under law, rule or regulation.
- 3.13 Marketing should be capable of substantiation either by reference to the approved labeling or by scientific evidence. Such evidence should be made available on request to healthcare professionals. Companies should deal objectively with requests for information made in good faith and should provide data which are appropriate to the source of the inquiry.

4. MARKETING MATERIALS

- 4.1 All printed material (including journal advertising and Internet posting) which is issued for marketing purposes by the manufacturer or with his authority should include the following: -
 - (a) the name of the device (normally the brand name) and, if applicable, the model number;
 - (b) the name and contact information of the manufacturer or his authorized agent, or the business name and contact information of the part of his business responsible for the sale; and
 - (c) a summary of use, if included, must be based on which the device is intended according to the data supplied by the manufacturer on the labeling.

- 4.2 Marketing material should conform, both in text and illustration, to canons of good taste and should recognise the professional standing of the recipients.
- 4.3 Where appropriate, for example, in technical and other informative material, the date of printing or the last review should be stated.
- 4.4 The following principles shall apply to electronic marketing materials, such as websites, as well as to printed materials:
 - (a) the identity of the medical device 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. **SPONSORSHIP OF SYMPOSIA AND CONGRESSES**

Symposia, congresses and the like organized by universities and healthcare professional organizations 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 Guideline.

5.1 General Principles

- (a) A Member company who sponsors a symposium, congress or other promotional, medical/health care or educational programme that is organized by a university or healthcare professional organization (an "Event") shall ensure that 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. The scientific agenda shall be prepared and distributed to participants before the Event., The two-third time rule does not apply to the sponsorship of a breakfast, lunch or dinner Event of no more than 3 hours in duration covering a clear scientific agenda.
- (b) The fact of sponsorship by the company 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) Any support to healthcare professionals to participate, universities or organizations to organize any symposium, congress or programme

should not be conditional upon any obligation to promote any medical device or product sold by a Member company.

- (d) 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 should be disclosed
- (e) No company may organize or sponsor an Event for healthcare professionals (including sponsoring individuals to attend such Event) that takes place outside of their home city unless it is appropriate and justified to do so from the logistical or security point of view. International scientific congresses and symposia that derive participants from many countries are therefore justified and permitted.
- (f) Marketing information which appears on exhibition stands or is distributed to participants at international scientific congresses and symposia may refer to medical devices which are not registered in the country where the Event takes place, or which are registered under different conditions, provided that the following conditions are observed:
 - (i) The meeting should be a truly international, scientific Event with a significant proportion of the speakers and attendees participating from countries other than the country where the Event takes place;
 - (ii) Marketing material (excluding promotional aids) for a medical device not registered in the country of the Event should be accompanied by a suitable statement indicating the countries in which the product is registered and make clear that such product is not available locally; and
 - (iii) Marketing material which refers to the intended use information (indications, warnings etc.,) authorized in a country or countries other than that in which the Event takes place but where the product is also registered, should be accompanied by an explanatory statement indicating that registration conditions differ internationally.
- (g) Member may provide an educational grant to:
 - (i) the organizer of the Third Party Educational Event to defray the costs of running the Third Party Educational Event and/or to support attendance of HCPs at the Event;
 - (ii) a Healthcare Institution to support attendance of HCPs at the Event; and/or
 - (iii) a Professional Association to support attendance of HCPs at the Event.
- (h) Direct Sponsorship is not permitted. Member may only support attending

HCPs through Healthcare Institution or Professional Association provided the recipient of the grant makes an independent decision on selection of the attending HCPs.

5.2 Sponsorship

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

- (a) Save and except under paragraph 5.2(j), entertainment of any nature (including theatre, concerts or sporting events) is prohibited. Hospitality should be reasonably related to the Event, “reasonable” in value (Appendix), and in any event, limited to travel, meals, accommodation and genuine registration fees.
- (b) Member companies have the duty to understand and adhere to policy on sponsorship of travel issued by institutions to which such healthcare professionals belong.
- (c) Any registration fees sponsored shall be related to the support of the scientific agenda of the Event, and not for the provision of entertainment, leisure or social activities inconsistent with paragraph 5.4(j).
- (d) No payments are made to compensate healthcare professionals for time spent in attending the Event.
- (e) Any sponsorship provided to individual healthcare professionals must not be conditional upon an obligation to prescribe, recommend, purchase, supply, use or promote any medical device.
- (f) Companies should not pay any costs associated with individuals accompanying invited healthcare professionals.
- (g) Payments of professional fees in the form of honoraria and reimbursement of out-of-pocket expenses both of which are legally permissible and reasonable by the locality’s standards, including travel and accommodation, may be provided to healthcare professionals who are providing genuine services as chairs, moderators, speakers or presenters on the basis of a written contract with the company at the Event.
- (h) 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.
- (i) 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 “reasonable” in value (Appendix).
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- (i) No stand-alone entertainment or other leisure or social activities should be provided or paid for by Member companies at Events, except entertainment of “modest” value (Appendix) which is secondary to refreshments and/or meals is allowed, or any other exceptions as stated in the Appendix notwithstanding the foregoing Event participants (including representatives from member companies) may pay on their own any stand-alone entertainment , leisure or social activities so long as they are in good taste and shall not bring the industry or any member company into disrepute.
 - (j) Members may provide or support training and education to HCPs on product-specific technology deployment, use, and application to facilitate the safe and effective use of medical technologies. Members may also provide or support education to HCPs on topics concerning or associated with the use of their medical technologies. Examples of training and education programs include “hands-on” training sessions, workshops, lectures, and product presentations. Training and education shall be conducted by qualified personnel, which may include Member personnel with appropriate technical expertise or personnel of an independent, reputable, professional third party.

6. MEDICAL REPRESENTATIVES

- 6.1 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.
- 6.2 Medical representatives should at all times maintain a high standard of ethical conduct in the discharge of their duties.
- 6.3 The requirements of the Guideline which aim at accuracy, objectivity, fairness, balance and good taste apply to oral presentations as well as printed or electronic material.
- 6.4 Medical representatives should not unfair or misleading comparisons or comparisons implying an advantage which is not in fact justified.
- 6.5 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.

- 6.6 Medical representatives should take adequate precautions to ensure the security of medical devices in their possession. They should also report to their company any information which they receive on the use of products and particularly reports of adverse incidents.
- 6.7 Companies should prepare detailed briefing material for medical representatives on the technical aspects of any product which the medical representative is to promote.
- 6.8 The system of remuneration of representatives should not be such as to adversely influence the proper prescribing and use of medical devices by the healthcare professional.
- 6.9 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 marketing purposes without the prior approval of the responsible person in the company – see Section 3.9.

7. FREE SAMPLES FOR PROFESSIONAL TRIAL

- 7.1 The distribution of product samples is intended for the use of healthcare professional to gain patient experience with a particular device, each sample pack shall be clearly indicated (i.e. professional sample, not for sale) The frequency and volume of samples provision should be reasonable given the professional's experience with the medical device and in any event, limited both in size and face value. Under no circumstances shall samples be included or used as part of any sale and purchase transaction of any medical device with any healthcare professional.
- 7.2 Samples shall only be given out in accordance with applicable policies of respective local healthcare institutions (e.g. Hospital Authority)
- 7.3 All samples sent by post should be packed up as to be reasonably secure against the package being opened by young children, and should be of quantities small enough not to be dangerous to children.
- 7.4 Where samples of products restricted by law to supply on prescription or are classified as "professional use only" are distributed by a representative, the sample should be handed directly to the doctor or given to a person authorized to receive the sample on his behalf. A receipt bearing doctor/dentist/pharmacist's signature must be obtained for the quantity of samples supplied.
- 7.5 All samples should be stored in a locked and secure area and someone

should be assigned to be responsible for the procedures relating to the storage and balance of samples. Companies should keep proper records and sample receipts so as to show a reconcilable balance.

8. HOSPITALITY AND PROMOTIONAL ITEMS

- 8.1 Inappropriate financial, material or personal benefits (such as theatre, concerts and sporting events), including inappropriate or lavish hospitality, should not be offered to healthcare professionals to influence them in the prescription or use of medical devices. Subject to exceptions stated in Appendix, modest gifts of a personal nature not related to the professional practice may be given on a maximum of 3 occasions per healthcare professional in any calendar year in acknowledgement of significant festive holidays, for example, Chinese New Year, Mid-Autumn Festival and Christmas.
- 8.2 Promotional and marketing items of “nominal value” (Appendix), provided free of charge and on infrequent basis, are permissible as long as they are related to the healthcare professional’s work and/or entail a benefit to patients.
- 8.3 Text, reference-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 when they serve a genuine educational purpose are provided on infrequent basis and limited to the value specified in Appendix. Maximum expenditure of these items per company should be in a modest amount in a calendar year.
- 8.4 Gratuitous payments in cash or cash equivalents (such as gift certificate) must not be offered to healthcare professionals under any circumstances.

9. MARKETING RESEARCH

- 9.1 Methods used for marketing research should never be such as to bring discredit upon, or to reduce confidence in, the medical device industry. The following provisions apply whether the research is carried out directly by the company concerned or by an organization acting on the company’s behalf.
- 9.2 Marketing research should not in any circumstances be used as a disguised form of marketing and the research per se should not have as a direct objective the influencing of the opinions of the informant.
- 9.3 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 marketing.

- 9.4 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.

10. RELATIONS WITH THE GENERAL PUBLIC AND LAY COMMUNICATION MEDIA

- 10.1 Requests from individual members of the public for information or advice on personal medical matters must be refused and the enquirer recommended to consult his or her own doctor.
- 10.2 Information about medical devices 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 safety of the product.

11. CHARITABLE DONATIONS

- 11.1 Members may make donations of money, products, or services for charitable or other philanthropic purposes, or sponsor events where the proceeds are intended for charitable purposes, unless the donations are prohibited under applicable laws and/or codes of conduct. Charitable donations shall be made to bona fide non-profit entities, charitable organizations, missions supporting charitable projects, and to other organizations supporting charitable projects. A charitable donation must not be targeted to HCPs, nor used as encouragement or as a reward for a HCP using, recommending, purchasing, or prescribing a Member's products or services. All charitable donations shall be appropriately documented.

12. ADVISORY PROCEEDING

The advisory proceeding is established to provide a mechanism for providing an unbiased opinion on complaints of breaches of the Guideline. However, the Guideline has an equally, if not more important role in encouraging the implementation and monitoring of improved standards for marketing practices to prevent actions leading to breaches of the Guideline.

- 12.1 The Guideline is administered by a Guideline Practice Committee ("the Committee") which the Chairman of the Executive Board of HKMHDIA shall invite 3 disinterested members, including Directors/General Managers/Managing Directors of member companies.

Provided that there are valid reasons or justification, either company involved in the proceeding have the right to reject an individual member to be included in the Committee within 7 days of the appointment.

If, after best efforts, the two parties and the Chairman still cannot reach an agreement on the Committee composition, the Chairman will elevate the issue to the Executive Board of HKMHDIA for final resolution.

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

- 12.2
- (a) The advisory proceeding may be initiated by any member of the healthcare professions, a company or the public, acting in good faith within the spirit and intentions of the Guideline.
 - (b) All correspondence should be addressed to the Secretariat of HKMHDIA
 - (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, an organization or an individual) with a full mailing address (and fax number, if possible, for correspondence)
 - (ii) identify the company which allegedly breached the Guideline, and the name of any company personnel, product or products which are specifically involved.
 - (iii) provide evidence that an attempt has been made to communicate directly, and if possible to resolve the matter with the company alleged to have breached the Guideline.
 - (iv) give the source of the activity which is alleged to be in breach of the Guideline.
 - (v) give the date of the alleged breach of the Guideline 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 Guideline.
 - (vii) specify for each element which section(s) of the Guideline 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 party against which the complaint (“Complained”) is made should provide supporting evidence that the Guideline has not been breached. The Complained can be any of a corporation, an organization or an individual.

- (f) The Committee shall render a written decision preferably within 30 days of receipt of the complaint with supporting documentation in line with Section 12.2 (d) and (e), and shall promptly notify the parties of its decision, the reasons thereof, and recommendations in writing and by registered mail. The Committee may conduct its business in any manner it thinks fit, however, no legal representation is allowed should the Complainant or the Complained be asked to testify in person. The decision timeline of 30 days may be extended within reasonable limits should the Committee require additional evidence from complainant or the affected company.
 - (g) A non-refundable charge of HK\$5,000 will be payable by any complainant. This does not apply to a person or body outside the medical and healthcare device manufacturing industry.
- 12.3 If a party to the complaint may request the Executive Board of HKMHDIA to review a decision. Any party requesting a decision review shall notify the Chairman of Executive Board of HKMHDIA in writing within 30 days of receipt of the Guideline Practice Committee's decision.
- 12.4 If a request for decision review is not made within the period specified in Section 12.3, the decision shall be final.
- 12.5 Upon receipt of a valid request for decision review, the Executive Board of HKMHDIA shall select 4 disinterested members including the Chairman of the Executive Board of HKMHDIA, provided that the Chairman of the Executive Board of HKMHDIA is a disinterested member, 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 company considered by the Review Committee to Complainant if the complaint is unsuccessful, and to be borne by the Complained if the complaint is successful, in the opinion of the Review Committee.

Decisions are made by a simple majority of the Review Committee, with the Chairman having a casting vote.

- 12.6 The Review Committee may conduct its review in any manner it thinks fit, however, no legal representation is allowed should the Complainant or the Complained be asked to testify in person. The final decision is made by a simple majority. The Review Committee shall render a decision within 30 days of receipt of the request for a review and promptly notify the Executive Board of HKMHDIA and the parties to the review of its decision, the reasons thereof, and recommendations in writing and by registered mail. The decision of the Review Committee is final.

- 12.7 In rendering its decision, the Guideline Practice Committee or the Review Committee acts in an advisory capacity. An engagement rather than a disciplinary approach is favored in reaching and rationalizing the decision, and in recommending appropriate remedies that a party should take in conforming to the Guideline. The acceptance or rejection of a claim should be based on clearly stated reasons and, where appropriate, supporting data.
- 12.8 The final decision shall be presented by the Guideline Practice Committee or the Review Committee, whichever appropriate, to the Executive Board of HKMHDIA in its regular meeting.
- 12.9 In the case that the Complainant who breached the Guideline is a member of HKMHDIA, the Executive Board, according to relevant sections of Articles of Association of HKMHDIA, may raise question on whether the conduct of the company member is injurious to the character or interests of, or otherwise prejudicial to HKMHDIA or be derogatory to such members' position in society, and consider the expulsion of the Complainant.
- 12.10 (a) The Guideline of Practice Committee shall produce an annual report summarizing the complaints received and the final decision on all complaints. This report will be distributed to the members of HKMHDIA and relayed to such other interested parties or bodies as the Executive Board of Directors may decide e.g. Food and Health Bureau, the Department of Health, the Hospital Authority, medical societies and the Consumer Council. The identity of the Complainants and Complainant shall remain anonymous.
- (b) When a complaint is upheld and a breach of the Guideline is determined, or non-disputed by the company, and in the event of a grave and serious breach of the Guideline which is of public interest, HKMHDIA shall report the matter to relevant authorities of the government Hong Kong SAR.
- 12.11 Members of HKMHDIA agree that they shall follow the local dispute resolution procedures in Section 12 of the Guideline to adjudicate on any local dispute or complaint in relation to violation of the Guideline that may arise, and the Guideline shall have exclusive jurisdiction over such local dispute or complaint between Members.
- 12.12 Notwithstanding Clause 12.11, on local issue that is not stipulated in or regulated by the Guideline, and/or international issue that goes beyond the boundaries of one local country, Chairman of HKMHDIA may select not to receive the complaint.

13. OPERATIVE DATE

This fourth edition of the Guideline shall take effect on January 1, 2018.

Complaint Procedure (subject to details in the body of the Guideline)

Composition of the Guideline Practice Committee	<p>The Guideline is administered by a Guideline Practice Committee which the Chairman of HKMHDIA shall invite 3 members, including Directors/General Managers/Managing Directors of members companies</p> <p>Provided that there are valid reasons or justification, either company involved in the proceeding have the right to reject an individual member to be included in the Committee within 7 days of the appointment.</p> <p>If, after best efforts, the two parties and Chairman still cannot reach an agreement on the jury composition, the Chairman will elevate the issue to the Board of Directors for final resolution.</p> <p>The Committee shall have the authority to appoint the Chairman of the Committee. Decisions are made by a simple majority of the Committee, with the Chairman having a casting vote.</p>
The Complainant	<p>All correspondence with a non-refundable charge of HK\$5,000 should be addressed to the HKMHDIA Practice Guideline Committee of which the Complainant should:</p> <ul style="list-style-type: none">(i) identify himself (whether a company, an organization or an individual) with a full mailing address (and fax number, if possible, for correspondence)(ii) identify the company which allegedly breached the Guideline, and the name of any company personnel, product or products which are specifically involved(iii) give the source of the activity which is alleged to be in breach of the Guideline(iv) give the date of the alleged breach of the Guideline which must have occurred during the last twelve months of the date of making the complaint(v) specify the individual elements in any activity which is alleged to be in breach of the Guideline

	<p>(vi) specify for each element which section(s) of the Guideline is/are alleged to have been breached</p> <p>(vii) give the reason(s) for the complaint</p> <p>(viii) provide supporting evidence of the alleged breach(es)</p>
The Guideline Practice Committee	The Committee shall render a decision <u>within 30 days</u> of receipt of the complaint with supporting documentation and shall promptly notify the parties of its decision in writing and by registered mail.
Complainant / Complainee	Any party requesting a review of a decision of the Guideline Practice Committee shall notify the Chairman of HKHMDIA in writing <u>within 30 days</u> of receipt of the Committee's decision.
Composition of Review Committee	<p>Where a party requests for a review of decision of the Guideline of Practice Committee as aforesaid, the Chairman of HKMHDIA shall select 4 members, including himself, from member companies and 1 outside expert to convene a Review Committee to review the matter.</p> <p>Decisions are made by a simple majority of the Committee, with the Chairman having a casting vote.</p> <p>The cost of such an outside expert shall be borne by the company considered by the Review Committee to Complainant if the complaint is unsuccessful, and to be borne by the Complainee if the complaint is successful, in the opinion of the Review Committee</p>
The Review Committee	The Review Committee shall render a decision <u>within 30 days</u> of receipt of the request for a review and promptly notify the parties of its decision in writing and by registered mail. The decision of the Review Committee is final.

Appendix

Guidance on the meanings of the terms “Nominal”, “Modest” and “Reasonable” in the Guideline for activities taking place in Hong Kong.

Under Paragraph 8.2

1. “Nominal” means within a reasonable limit of HK\$150 per promotional and marketing item.

Under Paragraph 5.2 (a), 5.2(i), 5.2 (j) , 8.1 and 8.3 as appropriate

2. “Modest” means within a reasonable limit of:
 - a) HK\$400 entertainment, leisure or social activities per healthcare professional per Event.
 - b) HK\$400 per gift per healthcare professional per festive holiday; and
 - c) HK\$500 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 within a reasonable limit of, during or following Event with local healthcare professionals:
 - HK\$400 per attendee for breakfast or lunch, and a maximum of HK\$700 per attendee for dinner (excluding service charges/gratuities or incremental costs attributable to venue rental where necessary and identifiable),
4. In reference to 8.3, the value of text, reference-books, magazines, journals, or other items, scientifically and/or medically-related and/or educational in nature given by a Member company is limited to:
 - HK\$5,000 per hospital department or group practice per year.

THE ASSOCIATION WISHES TO DRAW THE ATTENTION OF MEMBERS TO DEALINGS WITH DOCTORS AND HEALTHCARE PROFESSIONALS EMPLOYED BY THE GOVERNMENT AND THE HOSPITAL AUTHORITY, 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 DOCTORS AND HEALTHCARE PROFESSIONALS.

**The Medical Device Marketing Practice Guideline
was adopted by the current membership of
The Hong Kong
Medical and Healthcare Device Industries Association Limited
at an Annual General Meeting on November 14, 2011**

Published by

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