

Code of Ethical Conduct for Interactions with Healthcare Professionals

Singapore Manufacturing Federation

Medical Technology Industry Group

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ABOUT SMF MEDICAL TECHNOLOGY INDUSTRY GROUP (MTIG)

The Medical Technology Industry Group (MTIG) was formed in 1998 by reputable Multinational Companies, as well as representative local companies operating in the Medical Technology Industry.

Over the years, its representation has been towards a more holistic approach to collaborate with all the existing and future stakeholders in Medical Technology Industry to facilitate a communication platform that will advocate safety, effectiveness and reliability in the developments of the Medical Devices to the end users.

For the future, Medical Technology Industry Group strives to grow its membership base with more strategic partners and be the representative voice in the Medical Technology Industry for addressing the industry concerns.

The MTIG aims to be the leading voice for the medical industry and related organisations, encompassing medical devices, equipment, instruments, diagnostics, and implantables, and serving as a vital forum and focal point to advance the interests of the industry and benefit the people MTIG serves.



1. PURPOSE

- 1.1 The purpose of this Code is to facilitate ethical interactions between Company and Healthcare Professionals in Singapore. Where a Company also conducts business other than Medical Technology business, this Code shall apply to interactions with Healthcare Professionals only to the extent related to the Company's Medical Technologies.
- 1.2 Ethical interactions between Companies and Healthcare Professionals provide many benefits, such as:
 - (a) Ensuring that medical decision-making is made in the best interests of the patient;
 - (b) Increasing public confidence in the Medical Technology industry.
 - (C) Enhancing patient access to the safe and effective use of Medical Technologies by ensuring appropriate training of Healthcare Professionals by Companies;
 - (d) Promoting innovation and the ongoing development of Medical Technologies through legitimate and transparent collaboration; and
 - (e) Facilitating an open and transparent business environment, free from the high costs of corruption.

2. GENERAL PRINCIPLES

2.1 This Code is based upon the following general principles:

Advancement	Companies' relationships with Healthcare Professionals must be for the purpose of advancing Medical Technology, innovation and patient care.
Integrity	Companies must interact with Healthcare Professionals in an honest, truthful, and fair manner.
Independence	Companies may not provide anything of value to improperly influence Healthcare Professionals; decisions of Healthcare Professionals must be based on the best interests of patients.
Appropriateness	Benefits provided by Companies to Healthcare Professionals must be modest and/or reflect fair market value, and be for legitimate purposes.
Transparency	Companies must be open regarding significant financial relationships with Healthcare Professionals.

2.2 To the extent that any provision of this Code conflicts with a provision of a law, regulation or Company policy. Companies shall comply with the provision that has the strictest requirement or highest ethical standard.

3. DEFINITIONS

3.1 In this Code:

Company	Means organisations that develop, manufacture, sell, market or distribute Medical Technologies in Singapore.	
Demonstration Product	Means products that are used for training of Healthcare Professionals or patient education.	
Evaluation Product	Means products provided for human use, either as free samples of single-use products, or loans of reusable products or capital equipment.	
Healthcare Professional	Means those individuals and entities that purchase, lease, recommend, use or arrange for the purchase or lease of, or prescribe Company's Medical Technologies. This includes both clinical and non- clinical individuals who make product-related decisions of the type described above and anyone with material influence over purchasing decisions.	
Medical Institution	Means hospitals, clinical departments and clinics.	
Medical Technologies	Means medical device products, technologies and related services and therapies used to diagnose, treat, monitor, manage and alleviate health conditions and disabilities.	

4. CONSULTING ARRANGEMENTS WITH HEALTHCARE PROFESSIONALS

- 4.1 Companies may engage Healthcare Professionals to provide services that support research and development to advance medical science, develop new technologies, improve existing products and services, educate on the safe and effective use of a Company's Medical Technologies, or enhance the quality and efficacy of patient care.
- 4.2 Consulting arrangements between Companies and Healthcare Professionals must comply with the following:
 - (a) A legitimate purpose for the services is to be identified in advance;
 - (b) Only the number of Healthcare Professionals reasonably needed to perform the services are to be engaged;
 - (C) Healthcare Professionals are to be selected based on their qualifications to perform the services and not based on the volume or value of business generated or potentially generated by them;
 - (d) Compensation paid to Healthcare Professionals must be consistent with fair market value for the services actually performed;
 - (e) Compensation is to be paid after the services have been performed and upon sufficient evidence of performance of the services;

- (f) Compensation should be paid by cheque or electronic bank transfer;
- (g) Research or clinical trial agreements to conduct non-clinical or clinical research, including post-market outcome studies, must be based on a clear scientific or medical justification for the research;
- (h) Agreements granting or assigning intellectual property rights to a Healthcare Professional must be based on the Healthcare Professional having made, or the expectation that the Healthcare Professional will make, a novel, significant, or innovative contribution to the development of a product, technology, process or method;
- (i) The services and any compensation to be paid are to be documented in a written agreement in advance of the services being performed; and
- (j) Consulting arrangements should be disclosed in advance and in writing to Healthcare Professional's Medical Institution or employer if required by applicable laws, regulations or rules, unless applicable laws, regulations, or rules specifically require disclosure to a different body, in which case disclosure should be made in accordance with the applicable laws, regulations, or rules.
- 4.3 Meals and refreshments provided to Healthcare Professionals by Companies in connection with consulting arrangements subject to this Provision 4 must comply with Provision 8 of this Code.
- 4.4 Travel arrangements provided to Healthcare Professionals by Companies in connection with consulting arrangements subject to this Provision 4 must comply with Provision 9 of this Code.

5. THIRD PARTY EDUCATIONAL CONFERENCES

- 5.1 A third party educational conference is a conference sponsored or conducted by or on behalf of an independent professional association, of an educational or scientific or policy-making nature and for the purpose of promoting scientific knowledge, medical advancement or delivery of effective healthcare.
- 5.2 Companies may support such conferences through grants to conference organizers and grants to Medical Institutions and independent professional associations to support individual Healthcare Professionals' attendance at the conference as delegates, subject to the following considerations:
 - (a) The support preserves the independence of medical education and is not be used as a means of improper influence or as an inappropriate inducement to a Medical Institution to purchase a Company's Medical Technologies or to improperly obtain any other advantages;
 - (b) Grants are made only following a written request for support, including sufficient information to allow Companies to evaluate the scientific and educational merit of the conference as well as the appropriateness of the venue and agenda;
 - (c) Sponsorship funding provided is proportionate to the overall costs of the conference;
 - (d) The conference agenda is detailed and does not include standalone entertainment, side trips, or other inappropriate activities, and the venue is conducive to the exchange of scientific or educational information;
 - (e) The support is consistent with relevant guidelines established by the conference organizer and any accrediting body;
 - (f) The conference organizer independently controls and is responsible for the selection of program content, faculty, educational methods and materials;

- (g) Companies must not offer or directly pay for, or reimburse, the expenses of any individual Healthcare Professional delegates to attend the conference and the grant must not inappropriately benefit individual Healthcare Professionals or provide for any private side trips, recreation, entertainment or lavish meals and accommodation. In addition, with effect from January 1 2018, Companies must not make registration and/or travel arrangements for the attending individual Healthcare Professionals;
- (h) Companies must not select or influence the selection of any Healthcare Professionals to attend the conference; and
- (i) All grant and sponsorship arrangements must be appropriately documented.
- 5.3 Meals and refreshments provided to Healthcare Professionals by Companies in connection with a third party educational conference must comply with Provision 8 of this Code.
- 5.4 Companies may purchase advertisements and lease booth space for Company displays at conferences.
- 5.5 Companies may sponsor satellite symposia at conferences and provide content and faculty for these symposia, provided that the arrangements are disclosed in writing in all materials relating to the satellite event. If Healthcare Professionals are engaged for these symposia, Provision 4 of this Code shall apply.

6. COMPANY-SPONSORED TRAINING AND EDUCATIONAL MEETINGS

- 6.1 Companies may provide or support training and education of Healthcare Professionals on the safe and effective use of a Company's Medical Technologies, including "hands-on" training sessions, cadaver workshops, wet lab sessions, live surgeries, lectures and presentations.
- 6.2 Such training and education meetings must:
 - (a) Be held in a location (e.g., a town or city) that is logistically sensible considering the location of the majority of participants and those providing the training and education;
 - (b) Be held in appropriate venues such as a Healthcare Professional's premises, Company's premises, or clinical, laboratory, educational or conference facilities (including hotel meeting rooms) that enable effective learning; the venue must not be selected because of its entertainment, leisure or recreational facilities;
 - (c) Be conducted by qualified personnel, which may include sales personnel with appropriate technical expertise or personnel of an independent, reputable, professional third party;
 - (d) Follow a robust educational agenda that limits free time to that necessary for reasonable breaks and meals or refreshments; and
 - (e) Not include or facilitate side trips, entertainment or other inappropriate activities.
- 6.3 Meals and refreshments provided to Healthcare Professionals in connection with training and education meetings subject to this Provision 6 must comply with Provision 8 of this Code.
- 6.4 When it is impractical or inefficient to provide training at or close to Healthcare Professional's premises (such as for plant tours or demonstrations of non-portable equipment), Companies may pay for travel and accommodation costs, pursuant to Provision 9 of this Code.

7. BUSINESS MEETINGS WITH HEALTHCARE PROFESSIONALS

- 7.1 Company representatives may meet from time to time with Healthcare Professionals to discuss product features, conduct contract negotiations, or discuss sale terms. Such meetings are subject to the following:
 - (a) Meetings should generally occur at or near Healthcare Professional's premises, although occasionally such meetings may take place at another mutually convenient location, provided it is conducive to the exchange of information;
 - (b) Incidental modest meals and refreshments may be provided by Companies, provided these comply with Provision 8 of this Code; and
 - (c) In exceptional cases where Healthcare Professionals are required to travel in connection with meeting Company representatives, travel arrangements made by Companies must comply with Provision 9 of this Code.

8. MEALS AND REFRESHMENTS

- 8.1 Companies may sponsor, organize or reimburse meals and refreshments in connection with consulting arrangements and other services provided by Healthcare Professionals to Companies, company-sponsored meetings and other business meetings, provided these comply with this Provision 8.
- 8.2 All meals and refreshments provided to Healthcare Professionals must:
 - (a) Be modest and reasonable by local standards;
 - (b) Adhere to the cost limits specified in Table 1 of Annex 1;
 - (c) Not include standalone entertainment or recreational activities, with any entertainment limited to modest background music or cultural performances;
 - (d) Be subordinate in time and focus to the business, scientific or educational purpose of the event or engagement; and
 - (e) Be provided only to Healthcare Professionals with a legitimate business, scientific or educational need to be in attendance and not to any spouse, relative or other guest of a Healthcare Professional who is not an independent attendee in his/her own right.

9. TRAVEL AND ACCOMODATION

- 9.1 When it is necessary for Healthcare Professionals to travel in connection with consulting arrangements and other services provided by Healthcare Professionals to Companies, company-sponsored meetings and other business meetings. Companies may pay for or reimburse reasonable travel and accommodation expenses, provided these comply with this Provision 9 of this Code.
- 9.2 Travel and accommodation arrangements must adhere to the following:
 - (a) The expenses must be limited to those that are necessary for Healthcare Professionals to perform the services or attend the conference or meeting giving rise to the need to travel;

- (b) If air travel is required, economy class tickets shall be provided for travel with an aggregate flight time of less than 6 hours. For air travel with an aggregate flight time of 6 hours or more, Companies may provide business class tickets. Companies shall not pay any expenses relating to upgrades in class of air travel, cash in lieu of airfares, or any expenses associated with non-commercial air travel. Flights shall be booked on the most direct route and the most logical fare, with arrival and departure times to be reasonable and based on the schedule of the event;
- (c) Whenever possible, Companies should make travel and accommodation bookings directly on behalf of Healthcare Professionals, rather than providing reimbursement to Healthcare Professionals;
- (d) When direct bookings are not possible, reimbursement may only be made for actual and appropriate costs incurred, and upon submission of original receipts or other adequate proof of payment;
- (e) Reimbursement should be made by cheque or electronic bank transfer;
- (f) Companies must not fund or arrange for a Healthcare Professional's vacation or other personal activities such as private side trips; and
- (g) Travel and accommodation must be provided only to Healthcare Professionals with a legitimate business, scientific or educational need to be in attendance and not to any spouse, relative or other guest of a Healthcare Professional who is not an independent attendee in his/her own right.

10. EDUCATIONAL ITEMS

10.1 Companies may occasionally provide to Healthcare Professionals branded or non-branded items of minimal value, in addition to medical textbooks, medical journals and anatomical models. These items must serve as a genuine educational function relating to the Healthcare Professional's practice or otherwise benefit patients.

11. BRAND REMINDERS, TOKENS OF APPRECIATION AND CULTURAL COURTESIES

11.1 Companies may provide brand reminders (promotional and marketing items or other Company-branded or product-branded items, which benefit patients or are related to a Healthcare Professional's practice), and tokens of appreciation and other cultural courtesies of nominal value, provided these comply with and are limited to the categories and limits specified in **Table 2 of Annex 1**. In no event may cash or cash equivalents be given.

12. GRANTS AND CHARITABLE DONATIONS (MONETARY DONATIONS AND/OR DONATIONS IN-KIND)

- 12.1 Companies may provide research and educational grants and charitable donations, provided that Companies:
 - (a) Adopt objective criteria for providing grants and donations that do not take into account the volume or value of purchase of Company's Medical Technologies made by or anticipated from the grant or donation recipient or affiliated Healthcare Professionals;
 - (b) Implement appropriate procedures to evaluate grant and donation requests against those objective criteria and to ensure that they are not used as a condition of purchase of Company products or to improperly obtain any other form of advantage;

- (c) Ensure that sales representatives do not control or improperly influence decisions around grants and donations, although they may provide input to help evaluate the suitability of a proposed grant or donation or recipient;
- (d) Do not provide grants or donation for inappropriate activities, such as holiday parties or entertainment activities;
- (e) Do not link the grant or donation directly or indirectly to the purchase of Company's Medical Technologies;
- (f) Provide the grant or donation in response to a written request from a bona fide charitable organisation or Medical Institution ;
- (g) Provide the grant or donation to the requesting charitable organisation or Medical Institution and not to individual Healthcare Professionals; and
- (h) Document the grant or donation provided.
- 12.2 In addition to the rules set forth above, the following rules apply to the specified grants and donations:

(a) Charitable Donations:

Companies may make monetary or in-kind donations to support:

- (i) bona fide charitable organisations and missions;
- (ii) non-profit organisations for charitable purposes, including those supporting indigent care, patient and public education; and
- (iii) events where the proceeds are intended for charitable purposes; subject to compliance with local laws and regulations.

(b) Educational Grants:

- (i) Companies may provide monetary or in-kind grants to Medical Institutions to support legitimate educational purposes, such as the medical education of Healthcare Professionals, or medical students, residents, and fellows, and education of patients and the public about important healthcare topics. In relation to fellowship grants, Companies shall not provide extra funding to individual fellows who had received funding from Medical Institutions under this Provision.
- (ii) Grants may not exceed the value necessary to achieve the educational purpose.

(c) Research Grants:

- (i) Companies may provide monetary or in-kind grants to Medical Institutions to support independent medical research with scientific merit for the purpose of advancing scientific and clinical information, improving clinical care, promoting improved delivery of healthcare, or to otherwise benefit patients.
- (ii) Sponsored research should have well-defined objectives and milestones that are documented in a research protocol or similar document.
- (iii) Grants should only be paid upon evidence of satisfactory completion of the research activities or at agreed milestones as documented in the research protocol or similar document.
- (iv) Company-initiated or directed research involving a Company's Medical Technologies is not covered by this Provision 12 and should be evaluated under the Provisions of this Code addressing consulting arrangements.

13. SAMPLES, DEMONSTRATION AND EVALUATION PRODUCTS

- 13.1 Companies may provide Medical Technologies to Medical Institutions and Healthcare Professionals free of charge for demonstration and evaluation purposes, provided that:
 - (a) They are not given or intended as an improper influence;
 - (b) Only reasonable quantities of samples of Medical Technologies should be supplied to Medical Institutions and Healthcare Professionals to familiarize them with the Medical Technologies and enable them to gain experience with the Medical Technologies in their practice. Samples should not be sold or used for clinical studies;
 - (c) Demonstration Products, if not meant for human use, should be marked "not for human use" or otherwise to indicate that they are solely for demonstration purposes;
 - (d) Evaluation Products are provided for a period or in quantities that is reasonably determined to enable adequate evaluation by a Medical Institution or Healthcare Professional. Companies shall retain title to all multiple-use Evaluation Products during the evaluation period and remove the multiple-use Evaluation Products from the possession of the Medical Institution or Healthcare Professional at the end of the evaluation period, unless the Medical Institution or Healthcare Professional purchases or leases the multiple-use Evaluation Products;
 - (e) Evaluation Products should be appropriately disclosed and documented; and
 - (f) Companies are responsible to develop and maintain their own systems of control and accountability for samples, Demonstration Products and Evaluation Products provided to Medical Institutions and Healthcare Professionals.

14. ENSURING EFFECTIVE CODE IMPLEMENTATION BY COMPANIES

- 14.1 In order to ensure effective implementation of this Code, Company should take the following steps:
 - (a) Appoint a senior executive responsible for oversight of the Company's compliance with this Code;
 - (b) Adopt practical, useful and meaningful policies, guidance and tools intended to ensure compliance with this Code;
 - (c) Ensure that employees receive effective and ongoing training and education on this code and on relevant Company policies;
 - (d) Ensure that Company's board of directors and senior management or other governing body have expressly committed to support this Code;
 - (e) should ensure that relevant employees receive effective and ongoing training and education on the Code and on relevant company policies for ensuring Code compliance;
 - (f) Institute appropriate internal monitoring and auditing mechanisms;
 - (g) Create safe mechanisms for, and encourage, employees to raise compliance related concerns; and
 - (h) Require that third party intermediaries (including consultants, distributors, sales agents, and brokers) who may interact with Medical Institutions and Healthcare Professionals in connection with a Company's Medical Technologies agree to conduct their interactions in accordance with applicable laws and regulations, and ethical principles at least as restrictive as those contained in this Code.

15. ADMINISTRATION OF THIS CODE BY MEDICAL TECHNOLOGY INDUSTRY GROUP

- 15.1 This Code shall be reviewed at least once every two years by the Medical Technology Industry Group Compliance Sub-Committee Members.
- 15.2 Should there be any concern or query regarding this Code, Companies shall directly contact the concerned member Company and/or Chairman of Medical Technology Industry Group Compliance Sub-Committee.

Effective date: 17th May 2017

ANNEX 1

Table 1

Meals & Refreshments with Healthcare Professionals

(Refer to Provision 8 of this Code)

Meal / Refreshment	Limit per person per meal				
Breakfast	S\$50				
Lunch	S\$80				
Dinner	S\$120				
Refreshments	S\$30				
The above meal limits:					

- Do not apply to meals taken outside of Singapore*; and

- Exclude service charges and GST.

*Companies shall follow the reasonable local meal limit of the foreign country where the meal is consumed.

ANNEX 1

Table 2

Provision of Brand Reminders, Tokens of Appreciation and Cultural Courtesies to Healthcare Professionals

(Refer to Provision 11 of this Code)

Occasions	Types	Limit per item per person
Brand reminders (Company-branded and product-branded)	Stationery items, nominal cost USBs and other storage devices containing solely medical information for educational purposes	S\$50
Tokens of appreciation	Plaque	S\$100
Major Festive Season* (Chinese New Year, Christmas, Deepavali, Hari Raya and Mid- Autumn Festival)	Food items (no alcohol)	S\$100 (max of 2 items per person per year)
Congratulatory event* (Opening of new Medical Institution)	Flowers and food items (no alcohol)	S\$150
Bereavement* (Limited to Healthcare Professionals and immediate family members)	Flowers	S\$150

* For Cultural Courtesies, the types of courtesies, limits on appropriate occasions, values and frequency are exhaustive.

The above amounts exclude GST and other applicable taxes.

FREQUENTLY ASKED QUESTIONS (FAQ)

Q1: Can I make monetary donation to a hospital to support their annual dinner and dance event?

A1: No. A Company's relationship with Healthcare Professionals must be for the purpose of advancing Medical Technology, innovation and patient care. Social activities or events such as a dinner and dance are not educational or scientific events and therefore, it is deemed as inappropriate for Companies to support such events.

Q2: If I engage a Healthcare Professional to speak at our training workshop, can I compensate them for their services?

A2: Yes, provided there is a written agreement in place prior to the training and the other requirements of <u>Provision 4 of this Code</u> are observed. Among other provisions, the compensation should represent a fair market value for the actual services performed.

Q3: Can I pay for my customers to play golf or have a Karaoke session?

A3: No. Under this Code, Companies are not permitted to pay for any entertainment or recreational activities for Healthcare Professionals. Companies are only allowed to support events that have a specific educational, scientific and/or medical purpose.

Q4: Can I purchase a bottle of champagne for my customer's new clinic opening?

A4: No. Under this Code, Companies are only permitted to purchase flowers or food items for new clinic openings with a value of no greater than S\$150.

Q5: May a member Company provide an item to a Hospital for a lucky draw to be held on Nurses' Day that it could not give to a doctor under this Code?

A5: No. A member Company cannot give away an item for a lucky draw that it could not otherwise give a doctor under **Provision 11 of this Code**.

Q6: Can I provide an iPAD as an educational item to a doctor if I download educational materials onto it?

A6: No. Under this Code, the item must serve a genuine educational function or benefit patients. An iPAD or other similar electronic devices such as smartphones and tablets, even if downloaded with educational materials, are not permissible as this would be a substantial personal benefit to a Healthcare Professional, and would not be necessary to communicate the educational content of the material.

Q7: During a third party conference overseas, my customer brought his wife to meet me and suggested that we go for a dinner after the meeting. Can my Company pay for the dinner?

- A7: Companies may only provide dinner to a customer based on the following criteria:
 - The meal must be provided for a business purpose (e.g. discussion of products, medical or scientificrelated topics);

- The restaurant venue must not be lavish or perceived negatively by public, and should be conducive for business discussions;
- Meal and drinks must be modest;
- Companies must not pay for a spouse if he/she is not an independent attendee in his/her own right; and
- Companies must not provide any standalone social and entertainment activities to a customer or his/her spouse.

Q8: Can I provide grant to a private clinic owned by an individual doctor to support his/her attendance at a third party conference?

- A8: No. Under this Code, Companies are not permitted to select or influence the selection of any Healthcare Professional to attend a third party conference. In this case, as the private clinic is owned by an individual Healthcare Professional, there is no clear separation between the private clinic and the Healthcare Professional, and it may be perceived that the Company is giving the grant to indirectly benefit the individual doctor.
- Q9: My Company is not directly sponsoring a Healthcare Professional to attend a third party educational conference, but is sponsoring a Medical Institution that will select its Healthcare Professionals to attend the third party educational conference. Is my Company allowed to make travel arrangements for the selected Healthcare Professionals upon request by the Medical Institution?
- A9: No. With effect from January 1 2018, your Company must not make registration and/or travel arrangements for Healthcare Professionals attending third party educational conferences.
- Q10: Can I pay for a doctor to fly business class if the doctor travels overnight even though the flight time is less than 6 hours (e.g. from Singapore to India)?
- A10: On the rare occasion that a Healthcare Professional must travel overnight, this may be permissible. However, this should be on an exceptional and infrequent basis. This Code provides for business class air travel only for a flight time of 6 hours or more in total.
- Q11: Recently our Company has newly launched a medical device in Singapore and before we can start selling to Hospital X. They have requested a device for evaluation purposes. Is Company allowed to provide the device free-of-charge to Hospital X?
- A11: The device may be provided free-of-charge to Hospital X in accordance with the requirements of **Provision <u>13 of this Code</u>**, which include:
 - The device must not be given or intended as an improper influence on Hospital X;
 - The device must be provided for a period and in quantities that are reasonably determined to enable adequate evaluation by Hospital X;
 - The device should be appropriately disclosed and documented;
 - Company is responsible to develop and maintain its own systems of control and accountability for the device provided to Hospital X.

- Q12: If I want to make a complaint regarding inappropriate behavior or practices of another member Company, how can I do so?
- A12: You may do so by contacting the member Company directly to resolve the issue.

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