

CODE OF ETHICS ON INTERACTIONS WITH HEALTH CARE PROFESSIONALS

ADOPTED BY THE TAIWAN ADVANCED MEDICAL TECHNOLOGY ASSOCIATION

1. Preamble:

The Taiwan Advanced Medical Technology Association (“TAMTA”) represents its member companies (collectively “Companies” and individually “Company”) that develop, produce, manufacture and market medical products, technologies and related services and therapies used to diagnose, treat, monitor, manage and alleviate health conditions and disabilities (“Medical Technologies”). TAMTA is dedicated to the advancement of medical science, the improvement of patient care, and, in particular, the contributions that high quality, innovative Medical Technologies make toward achieving these goals. TAMTA recognizes the obligation to facilitate ethical interactions between Companies and those individuals or entities involved in the provision of health care services and/or items to patients, which purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe Companies’ Medical Technologies in Taiwan (“Health Care Professionals”).

To achieve the above goal, TAMTA has established the Code of Ethics (“the Code”), effective August 31, 2015.

1.1 The Purpose of the Code of Ethics

Health Care Professionals’ first duty is to act in the best interests of patients. Companies can serve the interests of patients through beneficial collaborations with Health Care Professionals. To ensure that these collaborative relationships meet high ethical standards, they must be conducted with appropriate transparency and in compliance with applicable laws, regulations and government guidance. The obligation to facilitate ethical interactions between Companies and Health Care Professionals in order to ensure that medical decisions are based on the best interests of the patient. The ethical principles that govern these interactions are the subject of the Code.

1.2 The Scope of the Code of Ethics

Medical Technologies

Unlike treatment approaches using drugs and biologics, Medical Technologies are highly dependent upon “hands on” Health Care Professionals from beginning to end. For example, implantable Medical Technologies are often placed in the human body to replace or strengthen a body part. In other circumstances, Medical Technologies are noninvasive reagents, instrumentation and/or software to aid in the diagnosis, monitoring and treatment decisions made by Health Care Professionals. Many Medical Technologies work synergistically with other technologies, or are paired with other products that deploy devices

in the safest and most effective manner. Many Medical Technologies require technical support during and after deployment.

Interactions with Health Care Professionals

The scope of beneficial interactions between Health Care Professionals and Companies is broad and includes interactions intended to:

- Promote the Advancement of Medical Technologies. Developing and improving cutting edge Medical Technologies are collaborative processes between Companies and Health Care Professionals. Innovation and creativity are essential to the development and evolution of Medical Technologies, which often occur outside a Company's laboratory.
- Enhance the Safe and Effective Use of Medical Technologies. The safe and effective use of sophisticated electronic, *in vitro* diagnostic, surgical or other Medical Technologies often requires Companies to provide Health Care Professionals appropriate instruction, education, training, service and technical support.
- Encourage Research and Education. Companies' support of *bona fide* medical research, education and enhancement of professional skills improves patient safety and increases access to Medical Technologies.

2. Code of Ethics Compliance

All Companies are strongly encouraged to adopt this Code and to implement an effective compliance program. All TAMTA member companies should adopt the Code.

3. Company-Conducted Product Training and Education

Companies have a responsibility to make training and education on their products and Medical Technologies available to Health Care Professionals. "Training" means training on the safe and effective use of Medical Technologies. "Education" means communicating information directly concerning or associated with the use of Companies' Medical Technologies, e.g. information about disease states and the benefits of Medical Technologies to certain patient populations. Training and Education programs include, but are not limited to, "hands on" training sessions, cadaver workshops, lectures and presentations, and grand rounds. Companies should adhere to the following principles when conducting training and education programs concerning Medical Technologies for Health Care Professionals:

- Programs and events should be conducted in settings that are conducive to the effective transmission of information. These may include clinical, educational, conference, or other settings, such as hotels or other commercially available meeting facilities. In some cases, it may be appropriate for a Company representative to provide training and education at the Health Care Professional's location.
- Programs providing "hands on" training on Medical Technologies should be held at training facilities, medical institutions, laboratories or other appropriate facilities. The training staff used by the Company should have the proper qualifications and expertise to conduct such

training. Training staff may include qualified field sales employees who have the technical expertise necessary to perform the training.

- Companies may provide Health Care Professional attendees with modest meals and refreshments in connection with these programs. Any such meals and refreshments should be modest in value and subordinate in time and focus to the training and/or educational purpose of the meeting.
- Where there are objective reasons to support the need for out-of-town travel to efficiently deliver Training and Education on Medical Technologies, Companies may pay for reasonable travel and modest lodging costs of the attending Health Care Professionals. It is not appropriate for Companies to pay for the meals, refreshments, travel or other expenses for guests of Health Care Professionals or for any other person who does not have a *bona fide* professional interest in the information being shared at the meeting.

4. Supporting Third-party Educational Conferences

Bona fide independent, educational, scientific and policymaking conferences promote scientific knowledge, medical advancement and the delivery of effective health care. Companies may support these conferences in various ways:

- **Sponsorship of Health Care Professionals.** Companies may provide limited financial support to individual Healthcare Professionals to attend bona fide third-party educational conferences in the form of conference registration fees or reasonable travel and accommodation costs. Financial support may not be provided to the Health Care Professional, but may only be provided directly to the relevant conference organizer or vendor, such as a hotel, airline, or travel agency. Any financial support must be appropriately documented and preserve the independence of medical education. Financial support must not inappropriately benefit, or be used as a means to inappropriately induce, a Health Care Professional.
- **Conference Grants.** Companies may provide a grant to the conference sponsor. They may also provide grants to a training institution or the conference sponsor to allow attendance by Health Care Professionals. Companies may provide grants when: (1) the gathering is primarily dedicated to promoting objective scientific and educational activities and discourse; and (2) the training institution or the conference sponsor selects the attending Health Care Professionals who are in training. Such grants should be used to reimburse only the legitimate expenses for *bona fide* educational activities. The conference sponsor should completely control and be responsible for the selection of program content, faculty, educational methods and materials.
- **Conference Meals and Refreshments.** Companies may provide funding to the conference sponsor to support the provision of meals and refreshments to conference attendees. Any meals and refreshments should be modest in value, subordinate in time and clearly separate from the continuing medical education portion of the conference.
- **Faculty Expenses.** Companies may make grants to conference sponsors for reasonable honoraria, travel, lodging and modest meals for conference faculty members.
- **Advertisements and Demonstration.** Companies may purchase advertisements and lease booth space for Company displays at conferences, but they must still abide by the relevant

local laws and regulations.

5. Sales, Promotional and Other Business Meetings

Companies may conduct sales, promotional and other business meetings with Health Care Professionals. Often, these meetings occur close to the Health Care Professional's place of business. It is appropriate to pay for reasonable travel costs of attendees when necessary and/or to provide occasional modest meals and refreshments in connection with such meetings. However, companies may not pay for meals, refreshments, travel or lodging of guests or individuals accompanying Health Care Professionals or any other person who does not have a *bona fide* professional interest in the information being shared at the meeting. See Section 8 for detail principles related to the provision of meals associated with Health Care Professional business interactions.

6. Consulting Arrangements with Health Care Professionals

Companies may engage Health Care Professionals to provide a wide-range of valuable, *bona fide* consulting services through various types of arrangements, such as contracts for research, product development, development and/or transfer of intellectual property, marketing, participation on advisory boards, presentations at Company-sponsored training and other services. Companies may pay consultants fair market value compensation for performing these types of services, provided that they are intended to fulfill a legitimate business need and do not constitute an unlawful inducement. Companies should comply with the following standards in connection with consulting arrangements with Health Care Professionals:

- Consulting agreements should be written and describe all services to be provided. When a Company contracts with a consultant to conduct clinical research services, there should also be a written research protocol.
- Consulting arrangements should be entered into only where a legitimate need for the services is identified in advance and documented.
- Selection of a consultant should be made on the basis of the consultant's qualifications and expertise to meet the defined need.
- Compensation paid to a consultant should be consistent with fair market value in an arm's length transaction for the services provided and should not be based on the volume or value of the consultant's past, present or anticipated business.
- A Company may pay for documented, reasonable and actual expenses incurred by a consultant that are necessary to carry out the consulting arrangement, such as costs for travel, modest meals and lodging.
- The venue and circumstances for Company meetings with consultants should be appropriate to the subject matter of the consultation. These meetings should be conducted in clinical, educational, conference or other settings, including hotel or other commercially available meeting facilities, conducive to the effective exchange of information.
- Company-sponsored meals and refreshments provided in conjunction with a consultant

meeting should be modest in value and should be subordinate in time and focus to the primary purpose of the meeting. Companies should not provide recreation or entertainment in conjunction with these meetings.

- A Company's sales personnel may provide input about the suitability of a proposed consultant, but sales personnel should not control or unduly influence the decision to engage a particular Health Care Professional as a consultant. Companies should consider implementing appropriate procedures to monitor compliance with this section.

7. Prohibition on Entertainment and Recreation

Company interactions with Health Care Professionals should be professional in nature and should facilitate the exchange of medical or scientific information that will benefit patient care, and avoid the appearance of impropriety. A Company should not provide or pay for any entertainment or recreation event or activity for any Health Care Professional, including any companion of the Health Care Professional.

8. Modest Meals Associated with Health Care Professional Business Interactions

A Company's business interactions with Health Care Professionals may involve the presentation of scientific, educational or business information and include, but are not limited to, the different types of interactions described in Sections 3 through 6 of the Code. Such exchanges may be productive and efficient when conducted in conjunction with meals. Accordingly, modest meals may be provided as an occasional business courtesy consistent with the limitations in this section.

Purpose: The meal should be incidental to the *bona fide* presentation of scientific, educational or business information and provided in a manner conducive to the presentation of such information. The meal should not be part of an entertainment or recreational event.

Setting and Location: Meals should be in a setting that is conducive to *bona fide* scientific, educational or business discussions. Meals may occur at the Health Care Professional's place of business. However, in some cases the place of business may be a patient care setting that is not available for, or conducive to, such scientific, educational or business discussions. In other cases, it may be impractical or inappropriate to provide meals at the Health Care Professional's place of business, for example, (1) where the Medical Technology cannot easily be transported to the Health Care Professional's location, (2) when it is necessary to discuss confidential product development or improvement information, or (3) where a private space cannot be obtained on-site.

Participants: A Company may provide a meal only to Health Care Professionals who actually attend the meeting. A Company may not provide a meal for an entire office staff where everyone does not attend the meeting. A Company also may not provide a meal where its representative is not present. A Company may not pay for meals for guests or spouse of Health Care Professionals, or any other person who does not have a *bona fide* professional interest in the information being shared at the meeting.

Other principles: Depending on the type of business interaction or meeting, additional principles may apply, as described in other sections of this Code of Ethics. Specifically:

- Section 3: Company-conducted Product Training and Education.

- Section 4: Supporting Third-party Educational Conferences.
- Section 5: Sales, Promotional and Other Business Meetings.
- Section 6: Consulting Arrangements with Health Care Professionals.

9. Educational Items and Branded Promotional Gifts: A Company may not give Health Care Professionals cash or cash equivalents (e.g. gift vouchers), or gifts.

Within limits permissible by local laws or local business ethics, a Company may provide educational items or branded promotional gifts that are capable of use by patients or Health Care Professionals. Such educational items or branded promotional gifts should be of appropriate value and not beyond the responsibility of Health Care Professionals.

10. Research and Educational Grants and Charitable Donations

A Company may provide research and educational grants and charitable donations. However, a Company may not provide such grants or donations as an unlawful inducement. Therefore, a Company should: (1) adopt objective criteria for providing such grants and donations that do not take into account the volume or value of purchases made by, or anticipated from, the recipient; (2) implement appropriate procedures to ensure that such grants and donations are not used as an unlawful inducement; and (3) ensure that all such grants and donations are appropriately documented. A Company's sales personnel may provide input about the suitability of a proposed grant or charitable donation recipient or program, but sales personnel should not control or unduly influence the decision of whether a particular Health Care Professional or institution will receive a grant or donation or the amount of such grant or donation. Companies should consider implementing procedures to monitor compliance with this section.

Research Grants

Research provides valuable scientific and clinical information, improves clinical care, leads to promising new treatments, promotes improved delivery of health care, and otherwise benefits patients. In furtherance of these objectives, a Company may provide research grants to support independent medical research with scientific merit. Such activities should have well-defined objectives and milestones and may not be linked directly or indirectly to the purchase of Medical Technologies.

Company-initiated or directed research involving a Company's Medical Technologies (such as clinical study agreements) is addressed separately in Section 6.

Educational Grants

Educational grants may be provided for legitimate purposes, including, but not limited to, the examples below. As noted in section 4, a Company may make educational grants to conference sponsors or training institutions. A Company may not make educational grants to individual Health Care Professionals.

- **Advancement of Medical Education.** A Company may make grants to support the genuine medical education of Health Care Professionals participating in fellowship programs that are charitable or have an academic affiliation. (For additional considerations regarding educational grants, see Section 4.).

- Public education. A Company may make grants for the purpose of supporting education of patients or the public about important health care topics.

Charitable Donations

A Company may make monetary or Medical Technology donations for charitable purposes, such as supporting indigent care, patient education, public education or the sponsorship of events where the proceeds are intended for charitable purposes. Donations should be motivated by *bona fide* charitable purposes and should be made only to *bona fide* charitable organizations or, in rare instances, to individuals engaged in genuine charitable activities for the support of a bona fide charitable mission. Companies should exercise diligence to ensure the *bona fide* nature of the charitable organization or charitable mission.

11. Evaluation and Demonstration Products

Providing products to Health Care Professionals at no charge for evaluation or demonstration purposes can benefit patients in many ways. These benefits include improving patient care, facilitating the safe and effective use of products, improving patient awareness and educating Health Care professional regarding the use of products. Under certain circumstances described below, a Company may provide reasonable quantities of products to Health Care Professionals at no charge for evaluation and demonstration purposes.

Company products that may be provided to Health Care Professionals for evaluation include single use (e.g. consumable or disposable products) and multiple use products (sometimes referred to as “capital equipment”). These products may be provided at no charge to allow Health Care Professionals to assess the appropriate use and functionality of the product and determine whether and when to use, order, purchase or recommend the product in the future. Company products provided for evaluation are typically expected to be used in patient care.

Single Use/ Consumables/ Disposables: The number of single use products provided at no charge should not exceed the amount reasonably necessary for the adequate evaluation of the products under the circumstances.

Multiple Use/ Capital: Multiple use products provided without transfer of title for evaluation purposes should be furnished only for a period of time that is reasonable under the circumstances to allow an adequate evaluation. The terms of an evaluation of such multiple use products should be set in advance in writing. Companies should retain title to such multiple use products during the evaluation period.

Demonstration products typically are not intended to be used in patient care. Demonstration products also are typically identified as not intended for patient use by use of such designations as “Sample”, “Not for Human Use” or other suitable designation on the product, the product packaging and/or documentation that accompanies the product.

A Company should provide Health Care Professionals with documentation and disclosure regarding the no-charge status of evaluation and demonstration products.

- **In case of any discrepancy between the English version and the Chinese version, the latter shall prevail.**