

Code of Ethics Regarding "Interactions with Health Care Professionals"

Adopted by the Taiwan Advanced Medical Technology Association

1. Preface:

The Taiwan Advanced Medical Technology Association ("TAMTA") represents member companies (hereinafter referred to as "companies") that develop, produce, manufacture, and market medical products, technologies, therapies, and related services and treatments (hereinafter referred to as "medical technologies"). These services and therapies are used to diagnose, treat, monitor, manage, and alleviate health conditions and disabilities. TAMTA commits to advancing medical technologies, as well as improving patient care, and achieving these goals through high-quality and innovative medical technologies. TAMTA also endeavors to facilitate the interaction between healthcare companies and healthcare professionals ("HCP") or organizations. These healthcare professionals or organizations refer to individuals and organizations that purchase, lease, recommend, use, and make arrangements for purchasing or leasing, or prescribe the medical technologies of these companies in Taiwan to provide health care services and programs for patients.

To achieve this goal, TAMTA has devised this "Code of Ethics" (hereinafter referred to as "the Code").

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1.1 Purpose

The key task for healthcare professionals is to make decisions that are in the best interests of patients. Medical companies work with healthcare professionals to service patients. To ensure that such partnerships meet high ethical standards, the collaboration must be reasonably transparent and compliant with relevant laws and government regulations. Companies have an obligation to meet ethical standards in their interactions with healthcare professionals to ensure that medical decisions are made in the best interests of patients. This Code of Ethics delineates the ethical principles that govern interactions between these parties.

1.2 Scope

Medical Technologies

Unlike drugs and biological therapies, the treatment process using medical technologies must rely on the operational skills of healthcare professionals, such as the use of implantable medical technology to replace or enhance the function of body parts. Other examples include non-invasive diagnostic reagents, instruments or software to assist in diagnosing, monitoring, and assisting medical staff in making

treatment decisions. Many medical technologies need to be supported by other technologies or used in conjunction with other products for safety and efficiency purposes.

Interactions with Health Care Professionals

Medical companies have extensive and beneficial interactions with healthcare professionals:

- Expediting progress in medical technologies. Partnership between medical companies and Health Care Professionals can promote the development and advancement of cutting-edge medical technologies. Development and innovation of medical technologies require originality and creativity, which are not attainable in the laboratory.
- Increasing safety and effectiveness of medical technologies. Medical technological products are complex; electronics, in vitro diagnostics, surgical or other medical technology products often necessitate companies to provide appropriate instructions, education, training, services, and technical support for healthcare professionals.
- Fostering research and education. Support for well-intentioned medical research, education, and professional technology advancement can improve patient safety and increase the use of medical technology.

2. Compliance

We encourage all companies to adopt this Code and compliance programs established by the Companies. TAMTA member companies should adopt and follow the letters and spirit of the Code.

3. Company-Conducted Education and Training

Companies have the obligation to provide education and training for healthcare professionals for their products and the medical technologies applicable to these products. "Training" refers to training for the safe and effective use of a product. "Education" refers to information about medical technology that is directly or indirectly involved in the use of products, such as disease awareness, or medical technology helpful to specific patient populations. Training and education programs include, but are not limited to, "hands-on" courses, dissection exercises / cadaver workshops, or in presentations or lectures forms. Companies that provide education and training courses in medical technology for healthcare professionals must comply with the following:

- The venue for courses and activities should be conducive to the effective communication of information, which can be medical institutions, academic venues, seminars, or other venues such as restaurants or rented conference facilities. Occasionally, company representatives may also provide education and training at the Health Care Professional's workplace.
- "Hands-on" training courses in medical technologies should be held in training facilities, medical institutions, laboratories or other suitable venues. The training faculty invited by the companies shall have relevant qualifications and professional capabilities. Technical training faculty may also include qualified sales personnels that are certified to provide such technical training.

- Health Care Professional Companies may offer appropriate meals and/or refreshments that are reasonable exclusively to participants of the Event and should be minimal and incidental to the main purpose of the event as education and training should be the focus.

If traveling is required for medical technology education and training, companies may provide healthcare professionals with reasonable transportation and accommodation support. However, companies should not cover food, refreshments, travel or other expenses for individuals accompanying invited healthcare professionals, or people unrelated to the purpose of the meeting or conference.

4. Supporting Third-Party Educational Research Conferences

"Third party educational research conferences" are conferences for well-intentioned independent, educational, scientific, and healthcare policy-making that help promote scientific knowledge, medical advancement, and effective healthcare which are typically organized by national, regional or professional medical societies/institutions and associations, medical trusts, continuing medical education providers, and hospitals and other medical institutions (collectively, "third-party educational research conference organizers"). Companies can support these conferences with:

- I. **Educational funding/contributions.** Companies may fund or donate to third-party educational research conference organizers or other appropriate third parties (such as training institutions, hospitals, medical or other professional associations, educational foundations, or other groups that support the training and education of Health Care Professionals) to reduce or reimburse conference expenses (hereinafter referred to as "educational funding/donations"). The companies only support educational funding/donations to third-party educational research conferences that promote objective scientific and educational events or presentations. Organizers of third-party educational research conferences shall have full control over, and responsibility for, the content of the course, selection of attending Health Care Professionals, and the educational methods and materials. Educational funding/donations may only be used to support genuine educational events and legitimate expenses associated with them.
- II. When a third-party educational research conference organizer or other appropriate third parties (as described in Section 4-I above) request educational funding/donations, only the third-party organizer or beneficiaries of the educational funding/donations other than the organizer may select and invite healthcare professionals who will receive support to attend the third-party conference. Companies may not take part in or attempt to influence the selection. Companies shall not provide educational funding/donations to support HCP attendance to a 3rd party conference in exchange for requesting or attempting to influence the decision to purchase, order, recommend or promote any product or medical technologyHealth Care Professional. Companies may also not ask for purchases, orders, recommendations, or promotion of any products or medical technologies as a condition for funding/donations. Companies should ensure that all support for third-party educational research conferences is properly documented. Following the conclusion of a third-party educational research conference, companies should consider requesting a report or statement on the use of the companies' educational funds/donations from the organizer. When making such requests, companies should not demand a list of specific healthcare professionals who benefited from the companies' educational funding/donations, unless it is for a genuine compliance audit, inspection, or investigation.
- III. **Meals and refreshments at the conference.** Companies may fund organizers of third-party educational research conferences to provide moderate meals and/or refreshments to attendees. Food and refreshments should be incidental to the main purpose of the Continuing Medical Education

conference.

- IV. **Faculty expenses.** Companies may sponsor third-party educational and research conference organizers for reasonable lecture fees, transportation, accommodation, and meals of the conference faculty (listed as lecturers in the conference and giving meaningful speeches/presentations in the conference). However, the companies may not inappropriately influence the selection of conference lecturers, or direct third-party educational research conference organizers to use educational funding/donations to compensate specific faculty.
- V. **Advertisement and display.** Companies may support commercial sponsorship to purchase advertisement media or booths at third-party conferences for the purpose of product display in compliance with all relevant local laws and regulations.
- VI. **Direct Sponsorship Ban.** "Direct sponsorship" means (i) companies' funding to specific Health Care Professional HCP to attend a third-party conference, (ii) companies select or influence in the selection decision of specific Health Care Professional HCP to attend a third-party conference, or (iii) companies have prior knowledge of the identities of the specific Health Care Professional HCP who will directly benefit from such sponsorship. Direct sponsorship typically involves the companies' direct funding of travel, lodging, food, transportation, conference registration fees, and other expenses to a Health Care Professional HCP, his/her Health Care Professional institution, or HCP appointed third-party service provider Health Care Professional (e.g., a travel agency).

5. Marketing, Promotion, or Other Business Meetings

Companies may hold marketing, promotion, or other business meetings with healthcare professionals relevant to the companies' products. Venues for such meetings should be convenient for the participating Health Care Professional HCPs to reach. If necessary, reasonable transportation and accommodation fees can be provided, and moderate meals and/or refreshments can be provided at the meeting. However, the companies should not cover any expenses such as meals, refreshments, transportation, or lodging for individuals accompanying invited guests, or guests unrelated to the purpose of the meeting. Please see Section 8 for details on meals during business interactions.

6. Consulting Arrangements with Health Care Professional

Companies may engage Health Care Professionals to provide various consulting services. Some examples include, research contracts, product development or intellectual property development or contract transfer, participation in marketing and advisory committees, or company-conducted training sessions and other services. On the premise that the service is based on reasonable and genuine business needs and does not constitute an unlawful inducement, companies may remunerate consultants a fair amount for the service. Companies should apply the following principles to all consulting arrangements with Health Care Professionals:

- All proposed services should be documented in a written consultation agreement. If the companies request Health Care Professionals to provide clinical research services, they should also sign a written agreement on a clinical trial research plan.

- Only consultative services that have been legally confirmed in advance and well-documented can be performed.
- Selection of consultants should be based on HCPs' qualifications and professional abilities.
- Remuneration for consultants should be in accordance with the fair market value in an arm's length transaction of the services provided and should not be based on the consultant's past, current or expected business volume or value.
- Companies may pay for expenses incurred by a consultant that are necessary to carry out the consulting arrangement, such as costs for travel, modest meals, and lodging, which must be reasonable, factual, and documented.
- The venue and setting of the meeting between the companies and consultants should be in line with the subject of the consultation. Such meetings should be held in clinical, educational, conference or other settings, including hotels or other business venues that are available and facilitate the effective exchange of information.
- Companies may provide appropriate food and refreshments in meetings related to consulting services. Companies may not provide entertainment in conjunction with these meetings.
- Companies' sales personnel may provide input about the qualifications of a proposed consultant but should not control or unduly influence the decision to engage a particular Health Care Professional as a consultant. Companies should consider implementing appropriate controls to ensure compliance with the provisions of this section.

7. Prohibition on Entertainment

Interactions between companies and health care professionals should be based on patient welfare and healthcare promotion, focusing on medical education or dialogue in medical science to avoid inappropriate outside perceptions. The companies shall not provide or pay for any entertainment for a Health Care Professional, including accompanying guests.

8. Meals During Business Interactions between Companies and Health Care Professionals

Interactions with Health Care Professionals may involve exchange of scientific, educational, or business information, including but not limited to those mentioned in Sections 3 to 6 of the Code. Companies should provide meals and refreshments in a manner conducive to the presentation or discussion of such information. Companies may therefore provide meals with due regard to business etiquette and shall comply with the restrictions set forth in this section.

Purpose: Meals or refreshments should be subordinate in time and in focus to discussion and presentation of scientific, educational, or business information. Meals should not be part of an entertainment.

Setting and Location: The dining setting should foster a genuine scientific, educational, or business

discussion. The venue can be the workplace of a Health Care Professional. In some cases, however, such workplaces may be patient care settings that are not conducive or unhelpful for discussing scientific, educational, or business information. In other situations, it may be impractical or inappropriate to provide meals at the Health Care Professional's workplace; for example, when (1) medical technology equipment cannot be easily transported to the Health Care Professional's workplace, (2) confidential information regarding product development or improvement must be discussed, or (3) no space for private conversation is available.

Attendees: Companies can only provide meals to Health Care Professionals who are actually participating in the meeting, and cannot provide meals to HCPs from the entire department or division who are not present at the meeting, nor in the absence of company representatives. Companies may not pay for meals for guests or spouses of Health Care Professionals irrelevant to the meeting.

Other Principles: The principles of other parts of the Code may apply, depending on the type of business interaction, especially

- Section 3: Product Education and Training Held by Companies
- Section 4: Supporting Third-Party Educational Research Conferences
- Section 5: Sales, Promotions and Other Business Meetings
- Section 6: Consultation arrangements with Health Care Professionals

9. Educational Items: No cash, cash equivalent (e.g. gift cards), or gifts to Health Care Professionals is permitted.

Companies may, to the extent permitted by local laws or local ethics guidelines, provide educational items to patients or Health Care Professionals that benefit patients or serve a genuine educational function for Health Care Professionals.

Except education items, company can't provide any non-educational items, branded reminders items, gift...etc.

10. Research and Educational Contributions and Charitable Donations

Companies may provide research and educational contributions, as well as charitable donations, but must not use such donations and contributions as an unlawful inducement. Accordingly, companies should: (1) use objective criteria in making such contributions and donations without regard to recipients' past or anticipated purchases in terms of volume or value; (2) implement appropriate procedures to ensure that such contributions and donations are not used as unlawful inducements; (3) ensure that such contributions and donations are properly recorded. Companies' sales personnel may advise on the appropriateness of potential recipients of the charitable donations or contributions, but should not exercise control over decisions or exercise undue influence over whether or not a particular person receives donations or contributions and the amount. Companies should consider appropriate procedures to monitor compliance with the provisions of this section.

Research Grants

Research can provide valuable scientific and clinical information, improve the standard of clinical care, lead

to promising new treatments, promote more healthcare advancements, and benefit patients. To achieve these goals, companies can make research grants to support independent third-party medical research of scientific merit. Such activities should have clear goals, objectives and milestones and should not be directly or indirectly related to the procurement of medical technology.

Section 6 sets out the relevant requirements for company-initiated research (such as clinical research agreements) that the companies initiate or manage with respect to their medical technologies.

Educational Grants

Companies may make educational contributions for legitimate purposes, including but not limited to the examples below. As stated in Section 4, companies may make educational contributions to conference sponsors or training institutions, but may not make individual educational contributions to Health Care Professionals.

- Continuing or medical education. Contributions may be made by companies to sponsor Health Care Professionals attending non-profit or academic education programs. (For other considerations for educational contributions, see Section 4.)
- Public education. On important healthcare topics, companies can provide contributions to support patient or public education.

Charitable Donations

Companies may donate money or medical technologies for charitable purposes, such as supporting low-income healthcare, patient education or public health education, or various activities whose proceeds go toward charitable ends. Such donations should be substantiated by a genuinely charitable purpose and should be limited to genuinely charitable organizations or (in rare cases) persons engaged in charitable activities in support of a genuinely charitable mission. Companies should conduct a substantive review to ensure that the charitable organization or charitable mission is true to its name.

11. Products for Evaluation and Demonstration Purposes

Providing products free of charge to Health Care Professionals for evaluation or demonstration purposes has many benefits to patients, including improving patient care, promoting the safety and efficacy of product use, increasing patient awareness, and teaching Health Care Professionals how to use the product. In the specified circumstances described below, companies may provide a reasonable number of products to Health Care Professionals for free for evaluation and demonstration purposes.

Products that may be provided to Health Care Professionals for evaluation include: single-use products (such as consumable or disposable products) and multiple-use products (sometimes referred to as "capital equipment"). These products may be available free of charge to allow Health Care Professionals to assess the suitability and functionality of the product and to decide whether and when to use, order, purchase or recommend the product. Products for evaluation are generally expected to be used in patient care in the future.

Single-Use/Consumable/Disposable Products: The number of products offered for free shall not exceed a reasonable amount required for evaluation.

Multiple-Use /Capital: Multiple-use products are provided for evaluation without transferring ownership shall be provided only for a reasonable evaluation period and quantities, and the evaluation period of the product shall be specified in writing in advance. Companies retain ownership of the products during the evaluation period.

Demonstration products are generally not intended to be used in patient care and are usually marked "Sample", "Not for Human Use" or other appropriate words on the product, the packaging and/or documentation that accompanies the product, indicating that such products are not intended for patient care.

Companies should provide documentation and instructions to Health Care Professionals for free evaluation and demonstration products.

- **This Code of Ethics is available in Mandarin and English. In the event of discrepancy, the Mandarin version always takes precedence.**