

## **Code of Ethics Regarding "Interactions with Medical 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 pharmaceutical products, technologies, related services and treatments (hereinafter referred to as "medical technologies"). These services and treatments 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 companies and healthcare individuals or organizations. These healthcare individuals or organizations refer to individuals and organizations that purchase, lease, recommend, use, and make arrangements for purchasing or leasing, or order 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").

Effective dates:

First edition: 2015-08-31

Second edition: 2022-09-01

### **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 medical professionals to service patients. To ensure that such partnerships meet high ethical standards, the collaboration must be appropriately transparent and compliant. 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 treatment modalities using drugs and biological products, the treatment process using medical technologies must rely on the operational skills of medical 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 diagnosis, 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 Medical Professionals**

Medical companies have extensive and beneficial interactions with medical professionals:

- Expediting progress in medical technologies. Partnership between medical companies and medical 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 medical 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 follow compliance plans developed by the companies. TAMTA member companies should adopt the regulations of the Code.

## **3. Company-Sponsored Education and Training**

Companies have the obligation to provide education and training for medical professionals for their products and the medical technologies applicable to these products. "Training" refers to training in 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 data, or medical technology helpful to specific patient populations. Training and education include, but are not limited to, "hands-on" courses, dissection exercises, or presentations or lectures. Companies that provide education and training courses in medical technology for medical 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 medical 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 personnel of companies shall hold relevant qualifications and professional capabilities. Technical training personnel may also be qualified sales members.
- For attending medical professionals, companies may offer appropriate food and refreshments that are reasonably priced and do not take too much time as education and training should be the focus.

If traveling is required for medical technology education and training, companies may provide medical

professionals with transportation and accommodation expenses within a reasonable range. However, companies should not cover food, refreshments, travel or other expenses for accompanying individuals, or people unrelated to the purpose of the conference.

#### **4. Sponsoring 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 sponsor these conferences with:

- I. **Educational funding/donations.** 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 medical 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 medical 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 medical professionals who will receive sponsorship to attend the third-party educational research conference. Companies may not take part in or attempt to influence the selection. Companies shall not provide educational funding/donations in exchange for requesting or attempting to influence the decision to purchase, order, recommend or promote any product or medical technology on medical professionals sponsored the conference. 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 medical professionals who benefited from the companies' educational funding/donations, unless it is for a genuine compliance audit, inspection, or investigation.
- III. **Food and refreshments at the conference.** Companies may fund organizers of third-party educational research conferences to provide reasonably priced food and refreshments to attendees. Food and refreshments should take a moderate amount of time, and not be part of the scheduled Continuing Medical Education conference.
- IV. **Teaching staff expenses.** Companies may sponsor third-party educational and research conference organizers for lecture fees, transportation, accommodation, and food of the conference teaching staff (listed as lecturers in the conference and giving meaningful speeches/presentations in the

conference) within a reasonable range. However, the companies may not inappropriately influence the selection of conference teaching staff, or direct third-party educational research conference organizers to use educational funding/donations to compensate specific teaching staff.

V. **Advertisement and display.** Companies can purchase advertising media or rent booths at third-party education and research conferences for the purpose of product display in a compliant manner with local laws and regulations.

VI. **Cessation of Direct Sponsorship.** "Direct sponsorship" means (i) companies' payment to specific medical professionals to attend a third-party educational research conference, (ii) companies' selection or influence in the selection of specific medical professionals to participate in third-party educational research conferences, or (iii) companies have prior knowledge of the identities of the specific medical professionals who will directly benefit from such sponsorship. Direct sponsorship typically involves the companies' direct payment of travel, lodging, food, other transportation, conference registration fees, and other expenses to a medical professional, the medical professional's institution, or a third-party service provider for the specific medical professional (such as a travel agency).

## 5. Marketing, Promotion, or Other Business Meetings

Companies may hold marketing, promotion, or other business meetings with medical professionals relevant to the companies' products. Venues for such meetings should be close to the participating medical professionals. If necessary, reasonable transportation and accommodation fees can be reimbursed, and appropriate food and refreshments can be provided at the meeting. However, the companies should not cover any expenses such as food, refreshments, transportation, or lodging for accompanying individuals, or persons unrelated to the purpose of the meeting. Please see Section 8 for details on food during business interactions.

## 6. Consultations with Medical Professionals

Companies may consult medical professionals through, for example, research contracts, product development or intellectual property development or contract transfer, participation in marketing and advisory committees, or company-sponsored training sessions and other services. On the premise that the service is based on reasonable business needs and does not constitute an illegal inducement, companies may remunerate consultants a fair amount for the service. Consultations with medical professionals should abide by the following standards:

- All proposed services should be documented in a written consultation agreement. If the companies request medical 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 qualifications and professional abilities.
- Remuneration for consultants should be in accordance with the fair market value of the regular

transactions for relevant services and should not be based on the consultant's past, current or expected business volume or value.

- Companies may pay the consultants necessary expenses for the performance of consulting services, such as travel, light meals, and lodging expenses, 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 advise on the suitability of consultant candidates but should not control decisions or exercise undue influence over them in order to place specific medical professionals as consultants. Companies should consider appropriate procedures to monitor compliance with the provisions of this section.

## **7. Prohibition on Entertainment**

Interactions between companies and medical 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 to any medical professionals, including accompanying personnel.

## **8. Meals During Business Interactions between Companies and Medical Professionals**

Business interactions between companies and medical professionals may involve the interpretation of scientific, educational, or business information, including but not limited to those mentioned in Sections 3 to 6 of the Code. This type of information exchange, when combined with meals, can be effective and efficient. Companies may therefore provide meals with due regard to business etiquette and shall comply with the restrictions set forth in this section.

**Purpose:** Meals should be incidental to scientific, educational, or business information presentation activities and should facilitate such communication. Meals should not be part of hospitality or entertainment.

**Setting and Location:** The dining setting should foster a genuine scientific, educational, or business discussion. The venue can be the workplace of a medical 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 medical professional's workplace; for example, when (1) medical technology equipment cannot be easily transported to the medical 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 medical professionals who are actually participating

in the meeting, and cannot provide meals to medical professionals who are not present at the meeting from the entire department or division, nor in the absence of company representatives. Companies may not pay for meals for guests or spouses of medical 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: Sponsorship of Third-Party Educational Research Conferences
- Section 5: Sales, Promotions and Other Business Meetings
- Section 6: Consultations with Medical Professionals

**9. Educational supplies, marketing giveaways and other branded items:** No cash, cash equivalent (e.g. gift cards), or gifts to medical professionals is permitted.

Companies may, to the extent permitted by local laws or local corporate ethics guidelines, provide educational supplies or branded items for patients or medical professionals. The supplies or items should be of appropriate value and should not exceed the responsibility of the medical professional. Branded gifts should be of low value, have a reasonable educational purpose or be related to the well-being of patients, and should also comply with the spirit of the "Code of Ethics and Integrity for Civil Servants".

## **10. Research and Education Contributions and Charitable Donations**

Companies may make research and educational donations, 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 donations or charitable 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 Donations**

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 donations to support independent medical research of scientific merit. Such activities should have clear goals and milestones and should not be directly or indirectly related to the procurement of medical technology.

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

### **Educational Donations**

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 medical professionals.

- Continuing or medical education. Contributions may be made by companies to sponsor medical professionals attending charitable or academic education programs. (For other considerations for educational donations, see Section 4.)
- Public education. On important healthcare topics, companies can make donations 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 motivated 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 medical 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 medical professionals how to use the product. In the specified circumstances described below, companies may provide a reasonable number of products to medical professionals for free for evaluation and demonstration purposes.

Products that may be provided to medical 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 medical 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 Products/Capital Equipment:** When multiple-use products are provided for evaluation without transferring ownership, new products shall be provided after a reasonable evaluation period, and the evaluation period of the product shall be specified in writing in advance. Companies retain ownership of the products during the evaluation period.

Sample products are generally not intended for patient care and are usually marked "Sample", "Not for use in humans" or other appropriate words on the body of the product, product packaging and/or accompanying

documents, indicating that such products are not intended for patient care.

Companies should provide documentation and instructions to medical professionals for free evaluation and demonstration products.

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