Code of Interactions with Healthcare Professionals

Asociación Mexicana de Industrias Innovadoras de Dispositivos Médicos.
(Mexican Association of Innovative Medical Device Industries)
# Code of Interactions with Healthcare Professionals

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INTRODUCTION

The Mexican Association of Innovative Medical Device Industries (AMID) is a non-profit, non-governmental association of leading companies of the medical device and diagnosis systems industry that promotes progress of healthcare services in Mexico by providing access to the latest medical breakthroughs that promote life-quality improvement.

AMID associated companies include the main global medical device and diagnosis systems companies, who are bound to abide to the code of ethics set forth herein.

Medical devices and diagnosis systems usually depend to a great extent on Healthcare Professionals active participation from the start to the end, unlike drugs or biological substances that act in the human body through pharmacologic, immunologic or metabolic means. Medical devices and diagnosis systems generally work as the extension of a physician’s hands, since depending on the circumstances, they assist Healthcare Professionals in the diagnosis, monitoring and treatment decision-making. Under other conditions, these devices create synergy with other technologies or products by assuring a safer and more efficient use thereof.

The scope of beneficial relationships between Healthcare Professionals and companies is broad and includes some foreseeable interactions. Some of the purposes of such interactions include:

- Promoting progress of medical devices and diagnosis systems. Development and improvement of state-of-the-art medical devices and diagnosis systems are collaboration processes between companies and Healthcare Professionals. Innovation and creativity are of essence for the development and evolution thereof, which usually occur outside companies’ laboratories.
- Reinforcing safe and efficient use of medical devices and diagnosis systems. The safe and efficient use of medical devices and diagnosis systems generally requires that companies provide Healthcare Professionals with proper instructions, education, training, service and technical support. Sometimes the regulatory authorities condition product approval to such training.
- Promoting research and education. Good faith support provided by companies to medical research, education and promotion of professional skills increases the patient’s safety and access to medical devices and diagnosis systems.
- Facilitating open and transparent environments where companies have a greater participation in global markets.

PURPOSE

This Code promotes ethical standards for medical devices and diagnosis systems addressed to Healthcare Professionals, in order to assure that the Associate member / Healthcare Professional relationship is not only appropriate but also avoids the appearance of inappropriate relationship. The guidelines described herein are consistent with provisions issued by international entities such as Eucomed, AdvaMed and APEC (Asia-Pacific Economic Cooperation) and are based on the following principles:

- **Integrity**: Acting honestly, sincerely and fairly towards all parties.
- **Segregation**: Healthcare Professionals relationships shall not be used to influence or skew through undue or improper advantages, any purchase decision, and this interaction shall not depend on sale transactions or on the use or recommendation of products owned by AMID’s Associates.
- **Consistency**: Agreements with Healthcare Professionals shall meet the commercial standards by being accurate, fair and corrupt-purpose-free.
- **Development**: Relationships with Healthcare Professionals are destined to thrust medical technology and innovation, and to take care and improve patient’s life quality.
- **Transparency**: Interactions with Healthcare Professionals shall have a clear purpose and scope, and shall always comply with domestic and local laws, regulations or professional codes of conduct.

Each associated company is responsible to ensure, through their key management, that all their employees are aware of these obligations and that all necessary measures intended to prevent, identify and report any infringement to this Code and to AMID’s Code of Ethics.

All AMID Associates must observe this Code and the association’s Code of Ethics.

If the local or federal laws, whether regulatory or otherwise, or any other Industry-related document – including Associates’ internal codes – contain more rigorous provisions than the ones contained herein, or are more rigorous as to anything regarding the interpretation thereof in any aspect whatsoever, such stricter provisions shall apply instead of the provisions hereof. If the local or federal laws are less rigorous than the provisions hereof, AMID Associates shall abide to the provisions set forth in this Code.

AMID Associates shall be responsible of following-up and verifying that any infringement to the Associate’s Code, procedures and guidelines is corrected and to assure that they create internal structures and procedures (including proper training to their employees and third parties) in order to assure that promotion activities are performed responsibly and ethically.

AMID is open to genuine complaints, regardless of the source that relates to any aspect of this Code, the foregoing according to the provisions of the operating procedures. If an infringement to this Code occurred, the main purpose should be to correct such infringement as soon as may be possible.
CHAPTER 1

1.1 — Definitions

a. AMID — Mexican Association of Innovative Medical Device Industries (Asociación Mexicana de Industrias Innovadoras de Dispositivos Médicos A.C.).

b. Associates — For the purposes hereof, means any legal entity that is a member of AMID.

c. Valuable Item or Good — Means any benefit or reward in money or in kind.

d. Medical Device — Means any substance, mixture of substances, material, apparatus or instrument (including the software required for proper use or application thereof) used alone or in combination with the diagnosis, monitoring or prevention of human diseases or ancillary to treatment thereof and of any disability, and those used to replace, correct, restore or change the human anatomy or physiologic processes. Medical devices shall include:

1. Medical equipment such as apparatus, accessories and instruments intended for a specific use and destined to medical, surgical attention or to exploration, diagnosis, treatment and patient-rehabilitation procedures, including those used to carry out biomedical research activities.

2. Prosthesis, orthotics and functional aid: Any device destined to substitute or supplement any human body function, organ or tissue.

3. Diagnosis agents: Any inputs including antigens, antibodies, calibrators, verifiers, reagents, reactive equipment, culture and contrast means and the alike that can be used as ancillary agents of other clinical or para-clinical procedures.

4. Odontology use inputs: Any substances or materials used in healthcare.

5. Surgical and healing materials: Any devices or materials that whether added or not with antiseptic or germicide materials are used in surgical practice or to treat continuity solutions, skin injuries or the alike.

6. Hygiene products: Any materials and substances applied on the skin or body cavities having a pharmacologic or preventive action.

e. Entertainment — Means any leisure activity intended to draw the attention of an audience or its participant.

f. Medical Equipment — Means the apparatus, accessories and instruments intended for a specific use and destined to medical, surgical attention or to exploration, diagnosis, treatment and patient-rehabilitation procedures, including those used to carry out biomedical research activities.

g. Governmental Entities — Means any public agency, organization or entity, either national, state or local, as well as any government-controlled companies.

h. Government Officer — Means any national or foreign government employee who is employed by any public agency or entity; this includes officers of the federal, state and municipal public administration, legislators of the judicial power, national or foreign health employees, customs officers, tax collection officers and employees of any other authorities related to health laws and other applicable laws and regulations. A government officer may also include any employee of hospitals affiliated to public education or military institutions, and any employee of governmental agencies working at a healthcare facilities or those who are involved with governmental entities and members of political parties or appointed candidates.

i. Modest or Reasonable Expenses — Means any expenses that are not deemed as luxurious, sumptuous or excessive according to the accepted average expenses within a geographic area, and related to the Fair Market Value thereof.

j. Sales Intermediaries — Means any individual or legal entity of Mexican or foreign nationality that acting in his/her capacity as shareholder, partner, Associate, representative, principal or attorney-in-fact, agent, distributor, member, commission agent, consultant, advisors, subcontractor, sales representative or employee, acting on behalf of any third party whether of the public or private industry, in the name or to the best of the interest of any Associate and who by virtue thereof is able to influence the behavior or decision of such third party, in order to draw or withhold businesses.

k. Related Parties — Means any individual that is related by blood or sentimental bond, including ancestors, descendant, common-low relatives, spouses, domestic partners and friends in general.

l. Undue Payments — Means bribes made to Healthcare Professionals (whether they are employed by the public or private sector) and to any public officer, governmental employee or of its related parties, which may be directly or indirectly made according to the following definition:

Bribe — Means the illegal action of offering, suggesting, promising or giving money, gifts or any other valuable good to a Healthcare Professional and/or government officer or their equivalent in the private sector in exchange of the performance or non-performance by such person of any action related to his/her duties or with the duties of any other Healthcare Professional and/or government officer, intended to get, obtain or handle businesses at the institutions where such Healthcare Professional and/or government officer is employed, with the intention to obtain or keep a benefit or undue advantage regarding other participants. Any bribe applies whether or not the money, gift or valuable good is accepted or received and regardless of the results obtained.

m. Healthcare Professionals — Means any professional, technician and assistant of any of the healthcare disciplines that may work within the public or private sector, including, without limitation, any of the following: Physicians (including all specialists and sub-specialists in current or future medicine disciplines), dentists, veterinarians, biologists, bacteriologists, nurses, social workers, chemists, psychologists, health engineers, nutritionists, dieticians, pathologists, and any other person working at administrative areas within a healthcare institution, such as: buyers, controllers, hospital managers, warehouse staff and any other person who is deemed as such under any other applicable laws.

n. Private Sector — Refers to Healthcare Professionals and private institutions.

O. Fair Market Value — Means the value of any payment or benefit paid in kind as fair and proper remuneration to a Healthcare Professional in exchange of his/her services, rights provided or work performed, taking into consideration commercially legitimate factors that can be objectively evidenced, expressly excluding certain aspects such as volume sales or value of any devotion or purchase.
2.1 — Relationships with Healthcare Professionals

AMID Associates agree not to directly or indirectly make, offer, promise or authorize payments in money or valuable goods, contrary to the provisions of the federal and local laws and of the anti-corruption conventions of which Mexico is a party, including institutional codes of ethics and the provisions of this Code, with the knowledge that the purpose of all or any portion of such money or valuable good would be to unduly influence any action or decision of such Healthcare Professional and/or government officer, client or of any other person. Likewise, no Associate may influence any Healthcare Professional and/or government officer, client or person to breach his/her statutory obligations or to unduly affect any authority action or decision.

AMID Associates undertake that any product promotion shall promote proper use of medical devices and diagnosis systems by objectively portraying such products in any advertising material, avoiding misleading advertising or exaggeration the properties thereof, which may lead Healthcare Professionals to errors in their decision-making processes.

Likewise, each Associate shall have internal policies defining the amounts that are consistent with the reasonability parameters of expenses set forth herein, according to the local regulations and to the provision of this Code. Associates may request Healthcare Professionals or government officers any documentation evidencing compliance with their internal policies or practices, to support any assistant provided.

2.2 — Meals

Associates may pay for meals of Healthcare Professionals during demonstration, education or training activities performed by Associates, in order to provide further information about their products. During work or business meetings, Associates may pay for meals of Healthcare Professionals and of any other attendants that are professionally related to the subject or information to be shared during the meeting.

Associates shall try that these meals are modest and casual offered at venues intended for such purposes (preferably within the same venue where the education activities are being carried out) without including or becoming part of any entertaining or leisure activity. The cost of meals of Healthcare Professionals or any health institutions’ employees that have not attended the event may not be paid for, neither the meals of their companions or related parties or of persons that have no professional interest in the information to be shared at such meeting.

2.3 — Entertainment

AMID Associates are committed not to organize, participate or sponsor entertainment or leisure activities, including sport, cultural or artistic events related to marketing or promotion meetings, education or training events.

2.4 — Gifts

AMID Associates may occasionally give modest gifts to Healthcare Professionals, related to their professional practice, for the benefit of patients or with an authentic education function.

Under no circumstance cash or equivalents may be given as a gift (such as gift cards) to Healthcare Professionals. Additionally, no gifts for their personal benefit may be given (including, without limitation, music CDs, DVDs, tickets to shows or sport events, electronic devices, etc.).

Associates shall record in their corporate books any gift made which shall be in proportion with the business and good-faith purpose thereof and always given on behalf of the company. Likewise, the cost of such gifts shall be reasonable and not be motivated to influence or obtain a benefit in exchange.

Limitation: AMID Associates shall use their best judgment taking into consideration all circumstances, having in mind that no gift shall be made to any person whose position may influence public procurement or tender procedures. Generally, Associates may give gifts observing the amounts set forth by the local laws and regulations, and those defined in their internal policies. This section does not apply to sample-giving practices for product evaluation purposes. In this regard, please refer to Chapter 6.
CHAPTER 3

3.1 — Events Sponsorship

Associates may provide funds in order to support medical science progress, patient and public education or independent medical research. However, it is important that the support provided to such programs (congresses, symposia, courses and complementary education events, also known as satellite symposia, as well as other promotional, scientific or professional meetings, hereinafter referred to as “events”) is not deemed as concessions to obtain special awards, rewards, as conditions to get a prescription or to purchase products or services from Associates. The purpose and focus of such events shall be to inform the Healthcare Professional about products or to promote scientific or academic information.

Consequently, Associates shall assure to keep proper documentation regarding all activities to be performed. None of the abovementioned events shall be conditioned to past, current or possible use of products or services and may only be offered to organizations or entities (and not individuals) entitled to receive them according to the national and local laws and regulations.

3.2 — Third Party Events

The events planned by a third party and providing educational, scientific knowledge or formulating standards promoting scientific knowledge and providing efficient healthcare may be sponsored by any Associates, also observing the guidelines set forth in their own internal policies. Such support shall remain independent from medical education and shall not be used as improper influence. Any expenses derived from sponsoring these events shall be directly paid to the organizer and/or services supplier (hotel, airline, etc.). Direct payment to Healthcare Professionals to attend this type of events is prohibited, since the same can be used and interpreted as an improper incentive. Speakers may be proposed only upon direct request of the conference organizer, and related to the same event.

In case of payments made for the attendance of a Healthcare Professional and/or governmental officer as speaker at such event, such payment shall be duly documented in a written request made by the organizer, who shall verify that such payment is destined to a legitimate educational benefit and that does not improperly benefit one or more Healthcare Professionals or government officers, or is not used to pay for travel, leisure, entertainment or accessories, or luxurious accommodations.

In turn, Associates shall control and keep internal records of any documentation related to such expenses (including reviews of the agenda and venue for the event). They shall have the request and authorization thereof before incurring in such expenses and shall assure safekeeping it. The purpose of any sponsoring activity shall be related to education events, excluding leisure, sports or entertainment events in general, and shall not include companions of Healthcare Professionals.

The conference organizer shall be responsible of controlling the contents of the program, speakers, methods and education materials. Associates may purchase advertisement and lease space for promotional booths during the events.

3.3 — Product Use Courses and Training (sponsored by any Associate)

Training courses and demonstrations provided by Associates shall have as main purpose to strengthen medical knowledge and safe and efficient training to use the products of any Associate. Such activities shall be performed by qualified personnel. Based on the foregoing, Associates may give courses, symposia, demonstrations and training to their distributors, clients and Healthcare Professionals, whether or not at their own facilities and for periods of more than one day. This type of events shall not promote leisure, recreation or entertainment.

When training at the facilities of any Associate or Healthcare Professional is impractical or inefficient, Associates may pay for transportation and lodging expenses, and may offer a reasonable price for meals during the duration of such training. Likewise, the organizer shall keep any documentation related to such events (agenda, list of attendance, related expenses and post-facto evidence) and the corresponding authorization, and shall not procure or make arrangements for companions or other guests of Healthcare Professionals that are not participating in the event.

Training activities shall be performed without this constituting a business commitment.

3.4 — Marketing and Promotional Meetings

When meetings are held to discuss products, negotiations or sales terms at venues other than the location of the Healthcare Professional (e.g., visits to manufacturing factories), the Associate may pay for reasonable transportation and lodging expenses according to the Associate’s internal policies regarding this matter, and according to the guidelines set forth herein. Regarding such information exchange meetings, reasonable meal expenses may also be covered.

Associates should not pay for expenses of guests or companions of Healthcare Professionals participating in such meetings.
3.5 — Travelling and Lodging

Paying for traveling and lodging expenses related to events, courses, product training, education or equipment demonstrations is appropriate, provided that the following requirements are met:

a. Transportation, lodging and meal expenses incurred in one day before the event and one day after the conclusion of the event, may be provided as long as the itinerary requires so.

b. Reasonable category hotels shall be used and in which their facilities are useful fit for the event. All participants shall stay in standard rooms.

c. First class flights are prohibited. All participants shall fly in coach class. Unless there is an evidenced medical condition requiring the participant to fly in Business Class, AMID Associates shall have prior written authorization of his/her immediate supervisor.

d. Paying for travel, lodging and meals of companions and/or visitors joining any Healthcare Professional is prohibited.

3.6 — Research

Associates may provide any support and/or hire the services of a Healthcare Professional for the performance of medical and/or scientific research, in order to promote clinical progress to the benefit of patients, provided that the same are according to the local laws and regulations, and upon compliance with the following requirements:

a. There shall be a prior written document addressed to the Associate requesting the research.

b. A formal research protocol shall be in place and all permits and authorizations necessary to carry out the same shall be obtained.

c. The agreement to be entered into to receive any support shall take into consideration the following, without limitation:

i. The research protocol shall specify the institution and investigators (related) who are responsible of carrying out the studies.

ii. The name and purpose of the study to be carried out.

iii. The clauses related to protocol compliance.

iv. Support sources and funding allotment.

v. Result reports delivery, both periodically and final.

vi. Sharing the results with the scientific community, including any adverse events.

Investigators shall have the necessary skills and abilities, and the institution shall have proper facilities to carry out the clinical trials in question. Compensation shall be determined according to the Fair Market Value and in no event regarding the volume or value of past, current or future businesses.

Likewise, the research shall have a well-defined purpose and term, and may not be involved in any manner whatsoever with past, current or possible trading of the Associate’s products or services.
CHAPTER 5

5.1 — Donations to non-profit organizations

Donations are part of the Associate’s commitment with the society and reflect our identity as responsible corporate citizens. All donations shall be made according to the following:

a. A previous formal request shall be documented, as well as the corresponding assessment evidencing that the donation is not given in exchange of undue influences or for improper events or activities.

b. Donations shall be given to private welfare institutions or other non-profit organizations duly authorized to receive such donations according to the local applicable laws. Donations may in no event be made to individuals or at the name of any Healthcare Professional.

c. The donation shall not constitute a trading advantage or a condition for past, current or future sales.

Associates shall take into consideration implementing procedures that assure proper donation-making and documentation.

CHAPTER 6

6.1 — Samples

Each Associate shall have internal policies covering proper delivery and use of samples. According to the local laws and regulations, free samples of a product for demonstration, evaluation, familiarization and/or education purposes related to the products in question can be delivered to any Healthcare Professional, in order to improve patient care. Such samples may not be sold or used for improper purposes, i.e. for purposes other than those referred to above. All samples:

a. Shall contain a label identifying it as such, differentiating it from products authorized for sale.

b. Shall be delivered in reasonable amounts and frequency allowing proper evaluation.

c. Shall not be a condition to sell or be understood as consideration for services.

Sample delivery shall be duly documented both before and after the delivery thereof.

6.2 — Demonstration Products and Equipment

Devices or products for demonstration purposes shall be delivered under free lease for reasonable periods of time, in such manner that the Healthcare Professional is able to properly assess them. Such deliveries shall be properly documented before and after in order to minimize risks of providing improper financial benefits to a Healthcare Professional. Companies shall assure that their demonstration products or devices are returned or properly discarded, according to their nature, at the end of the assessment period, unless the same are purchased.

Associates may request additional documentation in order to recover such equipment or products, according to their own internal policies.

CHAPTER 7

7.1 — Competition Issues

According to the provisions of the local laws in trade practices, unfair competition is illegal, more specifically, the following practices:

a. Determining prices, including coordinated efforts to determine price ranges, discounts or any other pricing element, including discussing price matters without fixing them.

b. Market positioning such as creating client groups or territories among competitors.

c. Research agreements or production quotas.

d. Exchanging competitive information, such as: prices, business plans, investment strategies, sales and product development, production volumes, distribution or sales, business relationships or current or future bidding processes.

AMID Associates must not carry out any of the abovementioned activities, whether between Associates or with third parties.

CHAPTER 8

8.1 — Legal Framework

The purpose of this Code is to determine self-regulatory practices among AMID Associates in order to comply with certain foreign regulations that apply to such Associates, whether due to the nature of their transactions, their shareholders or partners and/or due to the type of business of their related companies. The applicable foreign laws includes, without limitation, the Foreign Corrupt Practices Act (FCPA), and the 2011 UK Bribery Act. Likewise, this Code is intended to include some principles and compliance with local and federal laws currently in force in Mexico, including, without limitation the Mexican Federal Anti-Corruption Law (Ley Federal Anticorrupción en Contrataciones Públicas), the Federal Law of Government Officers Liability (Ley Federal de Responsabilidades de los Servidores Públicos), the Criminal Law (Código Penal) and relative laws and regulations of Mexico, including any other legal provisions that are not referred to herein but that apply to AMID and/or its Associates.

8.2 — Code Term and Modifications

This Code may not be modified or changed in full or in part, unless such modifications are set in writing and accepted by AMID’s Associates, according to its by-laws.

This Code became effective on July, 2009 and was amended on February, 2013, and shall be subject to review every two years.
Asociación Mexicana de Industrias Innovadoras de Dispositivos Médicos.
(Mexican Association of Innovative Medical Device Industries)