# CADIEM

**CAMARA ARGENTINA** DE INSUMOS, IMPLANTABLES Y EQUIPAMIENTO MÉDICO



# **CODE OF ETHICS**

## **PURPOSE**

#### **THIS CODE:**

- Sets the principles of proper business conduct and mechanisms to deal with various situations and issues that arise from the trade of health-related goods and services;
- Outlines the individual and corporate responsibility;
- Is available for consultation by all Associates, its officers and employees; as well as of those who deem it useful for making decisions which may affect the goods and services market of medical technology.

## DEFINITIONS

#### **HEALTHCARE PROFESSIONALS:**

Medical professionals, government officials concerned with healthrelated issues, officials of public or private institutions, whose decisions affect or define the choice or purchase of medical goods and services, officials of health-financing companies or organizations, or any individual or entity that buys, rents, recommends, uses, influences buying, defines it, or prescribes medical technology, equipment and/or services provided by health-related companies.

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#### Corporate integrity is part of the foundations of our behavior.

We understand that, while maintaining the highest level of corporate integrity through transparent, open, honest and fair agreements, we will earn the trust of those who contact us, whether they are customers, suppliers, competitors, colleagues or patients.

CADIEM is a Business Chamber that groups companies in the medical technology industry, by bringing together Small and Medium-size Enterprises (SMEs) and large companies, either national or foreign, working for the progress of medical sciences and patients' care. In particular, our Associates contribute to this through the provision of high-quality technologies at costs which are suitable for the healthcare system.

CADIEM associates (hereinafter, the "Associates") have the ethical principle of conducting business in accordance with high standards of business conduct, and in compliance with the laws and regulations in force in the Republic of Argentina. This principle is essential for the interactions of companies with institutions, medical professionals, government agencies and funders of the healthcare system. Associates respect the obligation of Healthcare Professionals to make independent decisions on the approval of use, purchase or use of medical technology goods and services.

As of March 7, CADIEM has adopted this Code of Business Ethics as the basic rule governing the interaction between associated companies and individuals, entities or institutions that buy, rent, use, recommend the use or rental, or prescribe the use of medical technology goods and services in Argentina. Honest and ethical business conduct makes our Associates to earn the trust and respect of customers, patients, suppliers, government agencies and regulatory agencies. Day-to-day business integrity is the indestructible basis of corporate integrity. This Code of Business Ethics has been agreed with the Associates and has been approved by CADIEM Board of Directors.

#### **2.1 MORE RESTRICTIVE STANDARD**

Associates agree to abide by the ethical principles included in this Code. This Code is subject to national and provincial laws and other codes of conduct applicable to the Associates.

If any law, internal procedure or other codes of conduct applicable to the Associates is more restrictive than the corresponding provision of this Code, Associates shall adhere to the more restrictive provision. In the same way, if a provision of this Code is more restrictive than the corresponding provision in any law, internal procedure or other applicable codes of conduct, Associates shall adhere to the more restrictive provision of this Code.

#### **2.2 PRINCIPLE OF TRANSPARENCY**

Associates shall appropriately document, in accordance with their internal procedures, any transfer of value directly or indirectly made to Healthcare Professionals and/or healthcare system institutions, both public and private, as well as any other agent of the healthcare system. This includes but is not limited to fees paid for services (e.g.: conferences, consulting, delivery of reports or scientific studies, medical or scientific reviews, training to other healthcare professional events, hospitality expenses offered on the occasion of an event, such as travel, enrollment or registration, accommodation and food expenses, and the provision of publications of medical-scientific nature, as well as donations or contributions made by the Associates, directly or indirectly, to any agent in the healthcare system.

There are multiple forms of interaction between companies providing medical technology products and services and healthcare professionals that go beyond selling, renting, recommending, using or prescribing the use of such products and services.

#### Some of such interactions are included below as an example:

#### • Research and Education:

Our Associates support medical research projects, education programs and programs for the improvement of professional skills, which help increase patients' access to new technologies, increase treatment safety levels, and improve the quality of care provided.

#### • Safe and Effective Use of Medical Technology:

The effective and safe use of medical technology, equipment or surgical devices, or other technologies in general, often requires our Associates to provide healthcare professionals with education, training, services or technical support.

#### • Development of Medical Technology:

The development of new technologies and the improvement of existing ones are processes that require collaboration and the joint work of our Associates and healthcare professionals.

#### Corporate ethics is the practice of our shared values

CADIEM recognizes that Associates can interact with Healthcare Professionals in other activities different from the purchase/sale, rental or prescription of medical technology products.

# CADIEM requires the following principle to be applied in all interactions between Associates and Healthcare Professionals:

"In no case shall interactions between Associates and Healthcare Professionals involve illegal practices or practices that may unduly influence the independent decision of the professional or official who is in charge of the purchase, rental, recommendation or prescription of their products and/or services."

Any compensation for services paid to any Healthcare Professional and/or health care institutions shall be consistent with the reasonable market value of the services rendered.

#### **3.1 PRODUCT TRAINING OR EDUCATIONAL EVENTS** SPONSORED BY COMPANIES

It is common that, given the nature of the products and services marketed, Associates have the need to carry out product-related education and/or training programs for Healthcare Professionals. These programs are sometimes conducted in locations which may require some participants to travel and which can last longer than expected.

## With respect to these training and/or education programs this Code establishes that:

- Educational programs should be conducted in a suitable environment for an effective transfer of knowledge; such an environment can be clinical, educational, a conference, and they can be conducted in hospitals, university centers, hotels, or other types of centers for business meetings.
- Training managers shall be individuals with appropriate qualifications and experience to conduct the training.
- Sponsor companies can offer courtesies to Healthcare Professionals in the form of meals or receptions, which shall be of reasonable value, and their cost, time and focus shall be in accordance with the educational or training purpose of the meeting.

- Sponsor companies can pay reasonable travel and accommodation expenses to Healthcare Professionals; such expenses shall be consistent with the purpose of training, and with a focus on the educational objective.
- It is not appropriate that sponsor companies pay compensation to Healthcare Professionals receiving the training for the time they will be spent on it. This does not cover those cases in which the Healthcare Professional is trained within the framework of a consultancy contract, for a purpose related to the subject matter of that contract.
- It is not appropriate for sponsor companies to pay for food, travel, or other guest expenses of Healthcare Professionals or any other individual who does not have a direct interest in the information provided at the educational meeting, such as relatives or friends of the guests.
- Meeting venues and duration should be dependent on the purpose of the conference as regards time and focus. In general, exotic, high-cost or sumptuous places are not considered reasonable.

# **3.2 THIRD-PARTY SUPPORT FOR EDUCATIONAL CONFERENCES**

Independent conferences on educational, scientific and consensus subjects are common and positive ways for promoting scientific knowledge, the advancement of medical techniques and the constant improvement of human healthcare.

These conferences are generally sponsored by international, national, regional, or specialty medical associations.

Associates can support this type of conferences in various ways, provided their own Codes and/or internal procedures or guidelines allow them:



Auspices or educational grants, either directly with the association organizing the Conference to help with related costs, or indirectly through a training institution or organizer appointed by the association for the event in question, in order to pay for the participation of students, grant holders, interns, or Healthcare Professionals.

These contributions will be acceptable only when the conference is primarily focused on the promotion of scientific or educational objectives. These allowances may only be paid to organizations and institutions with an educational purpose, and can only be used to cover expenses related to such an educational activity.

#### 3.2.2

Provided that their own Codes and/or internal procedures or guidelines allow it, Associates can, in certain circumstances, cover the costs of travel, accommodation and registration of Healthcare Professionals to participate in educational conferences held by third parties, when the conference is related to the area of expertise of the Healthcare Professionals, has international, national or regional relevance, and only if such costs are reasonable and their time and focus are in line with the purpose of the conference.

In these cases, a formal agreement shall be in place specifying that the purpose of the support is to contribute to ongoing professional training and is not intended to induce or create any commitment to purchase, recommend, use or prescribe the Associate's products.

#### 3.2.3

Receptions and meals: Associates can cover the costs for meals or receptions relating to the conference, but only if such expenses are reasonable and their cost is consistent with the conference, and their time and focus are in line with the purpose of the activity.



Time and focus of activities and their duration shall be in line with the medicalscientific purpose. Exotic, high-cost, spa or sumptuous places are not considered reasonable.

#### 3.2.5

Expenses associated with lecturers or instructors: Associates can cover conference costs relating to the speakers in the form of travel, accommodation, and food expenses. Professional fees may be paid if the professional is a speaker at a third-party congress and was hired by CADIEM Associate for such a purpose.

#### 3.2.6

Advertising and demonstrations: Associates may purchase advertising, or pay for the rental of exhibition spaces during conferences.

#### 3.2.7

It is suggested that all the activities described above are embodied in an agreement or document specifying the support or sponsorship provided, and accompanied by the scientific agenda.

#### 3.2.8

Under no circumstances shall Associates sponsor purely social, leisure and/or recreational activities.

#### 3.2.9

In no case shall Healthcare Professionals be paid for any loss of earnings, i.e., no money shall be offered to compensate for the time they spent to attend an event.



Support offered to third-party educational conferences from any agent in the healthcare system shall not be conditioned or related to the obligation on such an agent to prescribe, recommend, purchase or use a medical device.

#### 3.2.11

The support referred to in the preceding sections shall not include individuals other than the Healthcare Professionals involved.

#### **3.3 PROMOTION OR SALES MEETINGS**

It is common for Associates to have meetings with Healthcare Professionals to discuss about products or services, negotiate contracts and close sales. During such meetings, it is common for Associates to occasionally pay for receptions or meals involving Healthcare Professionals; however, this will only be acceptable when the cost is reasonable, and participants have a direct relationship with the purpose of the meeting. Payment of travel expenses is also acceptable where necessary (non-portable equipment demonstrations, demonstrations in specialized health centers, visits to manufacturing plants, etc.).

#### **3.4 CONSULTANCY AGREEMENTS**

Healthcare Professionals may be consultants to Associates, providing consultancy services, including research, monitoring of clinical cases or surgeries, making presentations at training sessions sponsored by the Associate or advising on products. It is appropriate for Associates to pay a reasonable compensation for this type of service, provided that there is a prior good faith consultancy agreement in place.

The following items are requirements for a good faith consultancy agreement between the parties:

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Consultancy agreements shall be in writing and signed by the parties; they shall specify the services to be provided, the term for the provision of services and the compensation to be paid for such services.

- Compensations paid to consultants shall be consistent with the fair market value for the services rendered.
- The number of consultants of a company may vary in accordance with the specialty and the type of consultancy services required; it should be a non-significant percentage of the total of professionals within that field.
- Consultancy agreements shall only be entered into where there is a legitimate purpose and need, clearly identified in advance, for the services required.
- The selection of consultants shall be based on their professional experience and qualifications to serve the purpose of counseling. It shall never be based on the business volume or value generated, or which could be potentially generated by the consultant.
- The scope and circumstances of Associates' meetings with consultants shall be in accordance with the purpose of the consultancy services required. These meetings are to be conducted in a professional manner in a clinical, educational environment, at conferences or even at hotels or other commercial meeting venues, and aimed at the effective exchange of information which is the purpose of consultancy.
- Meals or receptions offered during a consultancy meeting shall be affordable and consistent with the purpose of the meeting. Their time and focus shall be in line with the primary purpose of the meeting.
- Associates can make payments to consultants in compensation for the expenses incurred in the performance of their services, such expenses shall be reasonable and may include travel, food, accommodation and registration expenses incurred by Consultants, as long as they are directly related to the purpose of the services required.
- When an Associate hires research services from a consultant, a written research protocol shall be in place.
- The information specified above on consultancy agreements is independent of the relationship resulting from the hiring of healthcare professionals as employees, which is governed by labor law.

#### 3.5 GIFTS

Since medical technology services and products are usually funded by government health programs, or by funders who are not those who recommend or prescribe them, the requirements concerning courtesies and corporate gifts, targeting those who do recommend them, are subject to greater restrictions than in other industries.

Associates shall not offer gifts or payments in cash or any equivalent to any system agent or Healthcare Professional. However, gifts, or courtesies of reasonable value, such as business promotions, which are part of general business practice, may be occasionally offered, for example gifts that benefit patients or serve a genuine educational purpose, such as medical texts or models for educational use.

#### Useful tests to determine whether a gift is appropriate are:

- 1) The gift should not create any obligation of reciprocity to the person who delivers or receives it
- 2) The action should be able to be displayed and withstand public scrutiny
- 3) Its cost should be modest.

Gifts should generally be limited to items related to the practice of Healthcare Professionals or be educational in nature. Gifts that may personally benefit the Healthcare Professional shall be avoided.

This section does not address the legitimate practice of facilitating free samples for product assessment.

In certain situations, Associates may make donations for specific purposes, such as delivery of equipment or products to collaborate with healthcare, support for genuine scientific research for science progress, care of indigent patients, education of patients, public education, or sponsorship of events with charitable purposes.

Donations should be made only to legally established and duly registered organizations (for example: charitable organizations, public or private institutions engaged in healthcare, or primary care units), provided that their bylaws allow it, and the purpose is in accordance with the contents of this section.

Associates are not allowed to make this type of donations in order to induce Healthcare Professionals to purchase, rent, recommend, use or prescribe products and services.

#### It is not allowed to make donations in order to cover expenses that constitute daily activities and obligations of such entities (for example: building rentals, employees' wages, services, payment of taxes, etc.)

However, if the donation will be made to a social assistance or humanitarian institution and there are primary needs that are recognized and documented, this type of donation may be granted pursuant to the charitable programs of each Associate.

All donations shall be properly documented in an agreement or document specifying the donation made and making clear that it is not conditioned or related to an obligation on the beneficiary to recommend, purchase, prescribe, use, or influence the purchase of medical technology or equipment products and/or services provided by healthcare companies. Some examples of acceptable donations included in but not limited to this section are:

Grants to support genuine education of medical students, interns, attending physicians or other medical personnel.

Support for research with scientific purposes: Associates can offer auspices for the support of genuine scientific research. The objective of these donations shall be clearly documented.

Public education: Associates may sponsor educational programs for citizens in general or patients in particular, on healthcare topics. The success of CADIEM in the ranking of the Argentine market of healthcare supplies, equipment and services depends on its Associates' knowledge of and abidance to the legal and regulatory requirements governing their work. Compliance with laws and regulations along with the voluntary abidance of this Code of Business Ethics creates a solid base on which to build the corporate values that define us as a Business Chamber.

#### **5.1 LAWS AND REGULATIONS: COMPLIANCE**

The healthcare industry is a regulated and controlled activity, and involves all the functional business areas of the Associates. Regardless of the role played by an individual within a company, there are legal, regulatory and ethical standards that shall be complied with. Since regulations governing companies within the Medical Technology Goods and Services sector are mandatory, Associates shall be aware of those relating to their specialty.

#### **5.2 FAIR COMPETITION**

In Argentina, there are fair competition laws and regulations aimed at ensuring the acquisition of products, with the possibility of freely choosing them among a variety of goods and services at competitive prices, without inappropriate constraints such as pricing agreements between suppliers, monopolies, etc.

This Code of Business Ethics promotes compliance with applicable laws on fair competition.

Associates shall support ethical business practices and responsible corporate conduct, they shall not use any illegal methods, or methods which may unduly influence independent healthcare professionals' or officials' decision to purchase, rent, recommend or prescribe their goods and services.

Examples listed below provide some of the contexts related to anti-trust and fair trade laws:

Negotiations between competitors about prices, offers, discounts, promotions, benefits, costs, terms and conditions of sale are forbidden, as well as agreements between companies to divide territories or customers, limit supply or innovation.

- Companies should not make differences, in favor or against, any of their customers.
- Unfair competition methods and deceptive acts or practices are discouraged.
- It is not permitted to make statements about a product without data to support them.
- No false or misleading statements or comparisons about products and no unfounded belittling of a competitor or their products should be allowed.
- No one shall make their own product to look like it is from another manufacturer, simulating the packaging or the trademarks of a competitor.
- Participating directly or indirectly in the management areas or procurement departments of Health Institutions in order to influence the decision of Healthcare Professionals to purchase goods and services.
- Offering prizes or rewards of any kind in exchange for rejecting a competitor's product.

#### **5.3 ADVERTISING AND PROMOTION**

Advertising of medical technology products and services is subject to applicable regulatory standards.

Promotional material delivered to customers by means of printed information, through electronic, audiovisual or other means shall be accurate, truthful and correct and conform to the regulations in force in Argentina.

#### 6 Third Parties

This Code shall apply to any third party who enters into contracts or any type of agreement with the Associates for the promotion, co-promotion, agency, distribution and/or representation of any nature.

Associates shall take all reasonable and necessary steps in order to ensure compliance of third parties with the principles of this Code.

In the event of third parties' failure to comply with the principles of this Code, the Associate that has signed any of the agreements referred to above will be responsible for such a breach.

## **7** Respect for People

# CADIEM primary objective is a market where patients are treated with respect and dignity.

This essential principle for others is present in all aspects of our dealings with colleagues, physicians and other Healthcare Professionals.

#### **7.1 PROFESSIONAL ASSOCIATIONS**

CADIEM strongly believes in the service for the industry, and encourages individual and corporate participation in professional associations and organizations. By encouraging its Associates, Directors and employees to share their skills and experience with these groups, Associates invest in the success of the healthcare industry and its ethical and professional growth.

In the same way, CADIEM supports the exchange with other professional organizations such as medical and pharmaceutical associations, and scientific associations and other organizations related to the healthcare industry.

This Code of Business Ethics is a statement of the fundamental principles that govern Associates' decisions, which are intended to facilitate ethical behavior, and not intended to be, nor should be considered as, legal or professional advice of any kind. This Code is not intended to define or create any rights or categories thereof. Associates shall communicate this Code of Business Ethics to its agents and distributors so that they adhere to it.

### 8 Compliance Assurance

The Board of Directors of CADIEM along with the Compliance Committee shall ensure compliance with this Code, and shall have powers to work on the regulation of sanctions to be applied as a result of any breach of this Code.



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